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# WARRANT ARTICLE, 47

## STOCKPILE POTASSIUM IODIDE (KI) FOR THE PUBLIC

**To see if the Town will raise and appropriate, or transfer from available funds, including the Emergency Planning Fund provided to the Town annually from Entergy, a sum of money to obtain and to stockpile Potassium Iodide pills in the schools in a quantity sufficient to provide for each student and staff member, in the emergency shelters in a quantity sufficient to provide for the maximum capacity of each shelter, and at a municipal building for distribution to citizens of the Town; or take any action in relation thereto.**

# MEDICAL AND SCIENTIFIC BASIS

## PREPARED BY

**Mary Lampert, on behalf of the**
**Duxbury Nuclear Advisory Committee**
**January 2000**

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# Warrant Article, 47- YES

To see if the Town will raise and appropriate, or transfer from available funds, including the Emergency Planning Fund provided to the Town annually from Entergy, a sum of money to obtain and to stockpile Potassium Iodide pills in the schools in a quantity sufficient to provide for each student and staff member, in the emergency shelters in a quantity sufficient to provide for the maximum capacity of each shelter, and at a municipal building for distribution to citizens of the Town; or take any action in relation thereto.

## An Article to Protect Public Health and Safety

We have fire extinguishers in our homes, life jackets in our boats, and Ipecac in our medicine cabinets for our children. In a similar vein, we should have KI. We hope never to need it; but not to have it would be foolish.

## Who Supports Stockpiling KI for the Public?

### Leading Professional Organizations, including

- World Health Organization
- American Thyroid Association
- International Agency Atomic Scientists
- National Council on Radiation Protection
- Federation of American Physics
- Physicians for Social Responsibility
- Union of Concerned Scientists

### Statewide Public Interest Organizations, including

- Citizens Awareness Network
- C-10 Research and Education Center
- Clean Water Action
- MassPirg
- Massachusetts Citizens for Safe Energy
- Toxics Action Center
- Women's Community Cancer Project

### Physicians from Leading Teaching Hospitals, including

- Dr. Richard Clapp, former Director Massachusetts Cancer Registry, John Snow Research and Training Center, B.U. School of Public Health
- Dr. David Rush, Tufts University, Professor Emeritus Pediatrics, President Boston Physicians for Social Responsibility
- Dr. Ted Schettler, Boston Medical Center, Department Internal Medicine, author *Generations at Risk*, 1999
- Dr. Lowell Schnipper, Beth Israel Deaconess, Chief of Oncology

### Duxbury Committees

- Duxbury Civil Defense Director
- Duxbury Board of Health
- Duxbury Nuclear Advisory Committee

# Why Stockpile Potassium Iodide (KI)?

## Nuclear Accidents Can Happen, and Radioactive Iodine Will Be Released.

Chernobyl, TMI, and the recent nuclear accident in Tokaimura, Japan illustrate that nuclear accidents can happen even in a technologically advanced society.

The risk of an accident is greater than in the past, due to:

- aging of reactor components;
- economics of deregulation;
- lax oversight by regulators;
- on-site storage of high level nuclear waste at reactor sites;
- increased threat of terrorism with nuclear power plants as potential targets.

## Radioactive Iodine Can Cause Thyroid Cancer, Thyroid Disease and Mental Retardation, Particularly in Children.

Infants and the young are most vulnerable to radioactive iodine. Thyroid cancer in the young is more aggressive - spreading to the lymph and lungs. In pregnant women, Iodine passes the placenta freely.

The effects of a core-melt accident can extend many miles. For example at 10 miles from the plant, 70% of exposed adults and 100% of exposed children are likely to experience thyroid damage. At 25 miles, 40% of exposed adults and 80% of exposed children are likely to be injured.

## KI WORKS

KI provides almost complete thyroid protection if the recommended dose is taken just before or shortly after exposure. Taken within (1) hour after exposure, KI is 85% effective as a blocking agent; taken during the first 3-4 hours after exposure, KI is 50% effective as a blocking agent. But, there is no protection if KI is taken (6) or more hours after exposure.

**YES ON 47**

## KI is Safe and FDA Approved.

- KI is widely used. It is an ingredient in many cough syrups and expectorants. The incidence of adverse reactions to KI in doses used for nuclear accidents is as low as 1 in 10 million - often no more than a skin rash.
- After Chernobyl, Poland distributed about 18 million doses - about 95% of children and 23% of the adults were given one or more doses. Adverse effects were insignificant.
- Only those few people with a known allergy to iodide should consult with a physician before taking KI.

## KI Is Easy To Incorporate In Emergency Plans. It Is Cheap, And It Has a Long Shelf Life.

KI costs less than 10 cents a pill. It can easily be stockpiled in our schools, shelters, and made available for the public to pick up at a centrally located municipal office. It will last indefinitely if kept dry. Replacement is suggested every five to ten years.

## KI Is Stockpiled In Nations Around The World, But Not For The Public In Massachusetts.

In Massachusetts, KI is stockpiled only for emergency workers and institutionalized populations, such as prisoners.

KI is not carried in drugstores. There is not enough profit. You can only get it over the Internet, by mail or telephone.

Even if you have KI in your home, it will not do your children any good if an accident occurs during school hours. Without stockpiling, visitors to town would not be protected either; they would not have known to buy it. Families and teens on Duxbury Beach in the summer should be protected too.

# Contents


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American Thyroid Association, Inc.
Montefiore Medical Center
111 East 210th Street
Bronx, New York 10467

January 9, 1998

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Hoyle:

The American Thyroid Association (ATA) has been concerned about the issue of KI availability for many years and has endorsed the proposal for stockpiling. We have noted the amended petition for rule making filed by Peter G. Crane.

It is first necessary to say that the 30-day period allowed for public comment is insufficient, all the more so because it came during the holiday season. While the ATA's position on potassium iodide was ratified unanimously at the organization's annual meeting, we believe that many physicians may wish to write individual letters to the NRC as well. Having taken so many years to come to grips with the potassium iodide issue--the ATA has been writing to the NRC on this subject for almost ten years--the NRC hopefully can afford the interested public an additional 30 days in which to comment.

The ATA reiterates its previous comments to the NRC on the potassium iodide issue; the arguments in favor of KI were aptly summarized by Dr. Jacob Robbins, writing on behalf of the ATA to the Federal Emergency Management Agency on July 8, 1996:

1. The Chernobyl experience has shown us that thyroid cancer is indeed a major result of a large reactor accident, even when evacuation is carried out.

2. The post-Chernobyl Polish experience has shown us that large scale deployment of KI is safe.

3. The Three Mile Island experience has shown us that it is not easy to obtain an adequate supply of KI in an emergency.

4. The shelf life of properly packaged KI is extremely long.

5. The advantage of having a supply on hand for immediate use far outweighs its moderate cost.

6. The problems attendant on predistribution are immaterial for the matter of creating a stockpile;

7. No one questions the ability of KI to protect the thyroid from radioiodine.

8. Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown us that the exposure can continue for days; institution of KI blockade at any time in this period is beneficial.

With respect to Mr. Crane's amendment to his petition, the ATA continues to believe that it is essential that, one way or another, KI be available to protect the public, especially children, in the event of a nuclear accident or act of radiological terrorism. Mandatory inclusion of KI in emergency planning as proposed in Mr. Crane's original petition, is the surest way to accomplish this, and remains the ATA's preference. Under the amended petition, the Federal Government would couple an offer of free KI with a strongly worded recommendation to states that stockpiling of this medicine is both reasonable and prudent. We hope that Mr. Crane is correct in believing that states would not lightly reject this advice. The amended petition, while less than ideal in the view of the ATA, would nevertheless represent a significant improvement over current federal policy.

Finally, the NRC should be aware that its position on the KI issue is drawing critical attention both internationally and at home. In international meetings on thyroid issues and on the medical effects of Chernobyl, speakers have commented o the fact that the United States, virtually alone among developed nations, has failed to apply the principal health lesson learned from Chernobyl. Domestically, medical advisory committees in Maine and New York State have voted unanimously in favor of KI stockpiling. In both cases, the states have had to act on their own, obtaining the relevant information themselves. So far, the Federal Government, while asserting that the decision on KI is within the discretion of the states, has signally failed to give the states the information they need for a reasoned, informed decision.

Sincerely,

Martin I. Surks, M.D.
Secretary, The American Thyroid Association

cc: Paul J. Davis, M.D., President
David V. Becker, M.D.
John T. Dunn, M.D.

(212) 748-4580
525 East 68th Street, New York, NY 10021

The New York Hospital-Cornell Medical Center

Department of Radiology
Division of Nuclear Medicine

February 13, 1998

Dr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Hoyle:

I am a senior endocrinologist and nuclear medicine specialist with long experience in the management of thyroid disease and thyroid cancer. I have been particularly interested in the issues of radiation induction of thyroid cancer and have been a major participant in a wide range of studies on this issue ranging from the DOE/Brookhaven Marshall Islands Study, to studies of the effect of diagnostic and therapeutic radioiodine in the Thyrotoxicosis Followup Study and for the last 15 years have been working with the National Cancer Institute as a participant in their I- 131 Risk Assessment Studies and currently the Chernobyl/Children Thyroid Cancer Studies. I have been a member of the NCRP Committee that published monograph #80 on "The Induction of Thyroid Cancer by Ionizing Radiation" and am a member of the current NCRP Committee 1-8 revising that monograph. I have published extensively in the medical literature on thyroid cancer and its management, medical use of radioiodine and the usefulness of potassium iodide for thyroid blocking in the event of reactor accidents.

Early arguments against the stockpiling of KI for use in such an event have focused on the issues of possible toxicity from widespread use of potassium iodide, the difficult logistics of early distribution of KI and the question of cost/benefit ratio. Although all of those arguments have some cogency, the recent Chernobyl experience has nullified their pertinence. To date over 1200 children in the Chernobyl area have developed papillary thyroid cancer requiring major medical intervention. Although the certainty of the fallout initiation of these cancers cannot be fully confirmed until current dose assessment studies are completed, the remarkable coincidence and extraordinarily high incidence of this rare tumor in the Chernobyl area is convincing enough to require some action.

The concern about significant toxicity from potassium iodide in emergency blocking doses has been made moot by the extensive Polish experience where 18 million individuals received prophylactic potassium iodide with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects. Current packaging of KI in Europe has appeared to resolve the problems about shelflife and the blister packing that is used in Sweden is certainly effective and inexpensive. There are admittedly problems in effective and complete rapid early distribution and certainly in predistribution. However, should a reactor accident occur in the U.S. requiring KI and it not be available because of

an overly heavy emphasis on perceived difficulties, the resultant medical and political/sociological impact will be disastrous.

One cannot minimize the significance of a cluster of 1200 children with this serious and fortunately rare cancer. Although with modern intensive therapy results are good, such treatments often have very serious disrupting effect upon the life of the individual and such effects cannot be minimized. Long experience in personally taking care of hundreds of patients with thyroid cancer has convinced me of the importance of the disruption of the life of the individual with this disease.

The simplicity of having available a simple, inexpensive agent that can greatly lower the likelihood of this disease occurring is a fact that cannot be overlooked. Indeed, KI will not decrease whole body radiation and evacuation clearly is an optimal initial response to an accident, but it is not always possible and supplementation of evacuation with potassium iodide is undoubtedly useful. The Polish study showed that potassium iodide administration decreased the potential thyroid radiation dose by as much as 40% and this was given as late as 3 to 5 days after the initial exposure to fallout from the continuing fire at the Chernobyl plant.

It is difficult for me to understand the logic of not endorsing such a simple inexpensive prophylactic procedure as stockpiling KI. I strongly urge that you and the members of the Commission very seriously consider the potential impact of an admittedly unlikely accident in a nuclear power plant when the needed KI is not available. One can only go back to the Three Mile Island Accident and remember the frantic efforts to produce KI on short notice. The pharmaceutical industry responded remarkably to the sudden demand (which fortunately in the end was not needed) but the product they delivered had many defects including leakage from the caps, poor calibration of the dropper and a package that was difficult to use. Although fortunately such an event is unlikely, it nevertheless is potentially a major medical, sociologic and political disaster waiting to happen.

Sincerely,

David V. Becker, M.D.
Professor of Radiology and Medicine

fs

UNIVERSITY OF CALIFORNIA, SAN DIEGO

Department of Family & Preventative Medicine
School of Medicine
Mail Code 0628

9500 Gilman Drive
LaJolla, California 92093-0628

January 21, 1998

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Rulemakings and Adjudications Staff

Re: PRM-50-63

I am a physician, on the faculty of a medical school, with primary concerns with the health of families and the role environmental factors play in reproductive outcomes and the growth and development of infants and children. Recent studies have revealed an epidemic of thyroid cancers in children in the Chernobyl region, several years post-meltdown. Experimental studies in animals and clinical studies in Poland where over 10 million children and 7 million adults were administered potassium iodide (post Chernobyl ) provide convincing evidence of the efficacy and safety of community-wide administration of this material.

I urge the NRC to modify its regulation, 10 CFR Part 50 to specify that states and licensees include the provision of potassium iodide as a thyroid protecting drug for the general public. I believe this should be implemented on a federal level with uniformity of policy for all the states.

The Kemeny Commission Report on the Three Mile Island reactor release recommended that in addition to the original principles of safe siting and design/engineering features, potassium iodide be made available to optomize the protection of public health and safety. So many years have passed, and this recommendation has gone unheeded.

I appreciate that the administration of potassium iodide is not a panacea. It will not protect against many of the other radioactive isotopes -cesium 137, strontium 90, plutonium, etc., that could be released, with associated risk of increased leukemia, lung, breast and bone cancer, many years later. But we can do something about protecting against thyroid cancer. And we know that the very young are the most vulnerable.

Our best protection is to minimize opportunities for exposure to radioactive materials. In San Diego we have concerns, not only with the San Onofre Nuclear Power Plant in the northern part of our county, but the homeporting of three nulcear powered aircraft carriers right in San Diego Bay. It hardly seems like **safe siting** to place these nulcear power generators right in the center of California's second largest city, so close to our urban center with its commercial and government offices, and dense inner city neighborhoods. This area also includes our major tourist areas (the Gas Lamp district,

Point Loma and Coronado), and the city's transportation hub- (major airport, Amtrack station and bus and trolley terminals).

We know very little about the **design and engineering features** of our "nuclear" aircraft carriers- because their containment vessels and size are shrouded in scecrecy- justified by the Navy as a "national defense" issue.

As a physician concerned with protecting the public's health, I urge you to make Potassium iodide available to all communities around the United States where the potential of radioactive releases exists.

Ruth M. Heifetz, M.D., M.P.H.
Senior Lecturer
Occupaitonal and Environmental Health

**From:** lschnipp@caregroup.harvard.edu <lschnipp@caregroup.harvard.edu>
**To:** howard.koh@state.ma.us <howard.koh@state.ma.us>
**Date:** Tuesday, December 07, 1999 9:48 PM
**Subject:** stockpiling of KI

---

Dear Howard,

We are writing in support of the pre-distribution and stockpiling of KI as recommended by the WHO and numerous Massachusetts organizations and citizens.

Having read the literature, we are persuaded that it is imperative to stockpile KI in homes and public faciliies which are in the "near field" as well as those more distant from the reactors. As we understand the data, it is apparent that optimal protection of thyroid tissue requires almost immediate consumption of KI in order to block access of radioactive iodine to the thyroid gland.

We hope that you will act quickly and favorably on the suggestion that making KI readily available in the event of a nuclear emergency is imperative to protect the people of Massachusetts.

On a more private note, we hope that you and your family are well and that you are continuing to enjoy your position as Commissioner.

Lowell Schnipper, MD
Hester Hill Schnipper, LICSW
Beth Isreal Deaconess Medical Center

12/8/99

REVIEW

# Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks

JANUSZ NAUMAN, M.D., Ph.D., *Warsaw, Poland*, JAN WOLFF, Ph.D., M.D., *Bethesda, Maryland*

The accident at the No. 4 reactor of the Chernobyl Power Station took place on April 26, 1986, at 1:23 AM. Like the accident at Three Mile Island No. 2, the immediate cause was operator error, but the much more serious release consequences in the Ukraine can be ascribed to reactor design [1–3]. Two explosions occurred, the first due to steam and a second one due to hydrogen. The explosions expelled fission products and fuel elements to the exterior that accumulated in a cloud reaching to approximately 7,000 m and centered at approximately 4,500 m. Because the graphite ignited, there was a second, more prolonged but less intense, release over a 9- to 10-day period that peaked on May 6, 1986, and dropped sharply on May 11 as the fire was extinguished. The following volatile elements, as well as the noble gases xenon and krypton, constituted the most abundant released material: iodine, cesium, and tellurium. In this review, we will deal primarily with iodine isotopes as they affected Poland. Although iodine isotopes other than $^{131}I$ are present with higher core inventories [2,4], their short half-lives make them important primarily in the first days, and near the reactor. Spectroscopy of the environmental isotopes was not possible under the emergency conditions prevailing, but it was found that approximately 28% of the air radioactivity was present as short-lived isotopes of iodine as measured in Warsaw on April 28. Thus, some inhalation of short-lived iodine isotopes occurred during the earlier exposure period. Nevertheless, the timing was such that the protective actions were directed at $^{131}I$.

Initial Russian estimates of the amount of $^{131}I$ released from a core inventory of approximately 63 MCi were 7.3 MCi [5]. More recent measurements and calculations have raised that estimate to approximately 60% of the inventory and total releases of 36 to 46 MCi $^{131}I$ (1.3 to 1.7 ExaBq) [2,4,6,7]. In Poland, increased air radioactivity was first detected on the night of April 27 and 28 [7,8] and amounted to 504 Bq of radioiodines/$m^3$ air with 1.55- to 3.0-times higher values in northeast Poland. By 10 AM on the 28th, all Polish monitoring stations reported air, soil, and water contamination and were placed on 24-hour emergency alert. Spectra showed that the early air samples were approximately 80% iodine isotopes. Radioiodine depositions on the ground and grass in the provinces varied, but due to local rains, they were from 3.5 to 9 times higher than in Warsaw. Local sources (from research reactors) for the contamination could be ruled out and a serious accident to the east was suspected; this was confirmed by a brief report of the Tass News Agency on the evening of April 28, but its importance was minimized by the agency. Because of the environmental findings, 18 children received neck measurements at the Center for Radiological Protection, where sophisticated counting facilities were available. Thyroid counts amounted to 500 to 1,300 Bq by 11 AM, April 29. During the night of April 28, a governmental commission was called upon to assess damage potential and to recommend protective measures. Because reliable information was not available from Russia, decisions had to be based on a worst case scenario. After study of published response plans [9–14], and the ministerial recommendations [15], the following intervention levels were recommended by the commission on the morning of April 29:

(1) Whole body committed dose should not exceed 5 mSv/y (0.5 rem).

(2) Thyroid committed dose should not exceed 50 mSv/y (5 rem) in children (16 years and under) and 500 mSv/y (50 rem) in adults. The tumorigenicity of radiation to the thyroid has been calculated from external radiation, and it was believed that in children the risk decreases with increasing age. This has now been demonstrated in several studies [16–18]. Even though no similar data are available for internal radiation from $^{131}I$, and the effectiveness factor has been estimated to range from 1 to less than 0.1, it was decided to adopt the very conservative dose commitment of 50 mSv as the intervention level for children.

(3) Thyroid content in children 16 years or under should not exceed 5,700 Bq at any one moment.

Considering the high radioiodine uptakes in the population, and assuming continuing contamination, the commission concluded that, in eastern Poland, the annual committed thyroid dose in children under 16 might well exceed the 50-mSv limit, and that therefore, prophylactic potassium iodide (KI) should be considered. Some of the estimated contamination levels of the environment are summarized and compared with preaccident levels in Table I.

Measures to protect the thyroid gland against envi-

From the Department of Endocrinology (JN), University Medical School, Warsaw, Poland, and the National Institute of Diabetes and Digestive and Kidney Diseases (JW), National Institutes of Health, Bethesda, Maryland.

Requests for reprints should be addressed to Jan Wolff, Ph.D., M.D., National Institute of Diabetes and Digestive and Kidney Diseases, Building 8, Room 2A-25, Bethesda, Maryland 20892.

Manuscript submitted June 30, 1992, and accepted in revised form November 2, 1992.

ronmental radioiodine contamination have been well delineated in the past [9–14]. A salient point from all these studies is that prompt administration of stable iodine is highly desirable because iodide is rapidly concentrated and organified by the thyroid but is then stored for prolonged periods as iodinated thyroglobulin. Although some thyroid uptake had already occurred, stable iodine was still useful to protect the gland against the continuing contamination resulting from Chernobyl. Stores of KI available at Cefarm (the Central Pharmacy Organization) were sufficient for about 90 million doses of 100 mg of KI each. The chief aim of KI prophylaxis is to reduce the thyroid burden to an acceptable level. This could be done either by achieving a nearly total block of radioiodine uptake early, until high levels of contamination subsided, or by intermittent KI treatment after an initial dose according to subsequent contamination levels. This latter maneuver was used in the Polish population. In view of the limited supplies of KI, it was also believed that such a procedure would more readily permit reinstitution of KI prophylaxis if the level of contamination should increase again. Thus, at 12 noon on April 29, the Minister of Health gave orders to prepare KI solution in the centralized pharmacy for distribution to the 11 provinces most affected. This was to be made available through all hospitals, public health centers, schools, kindergartens, and so forth. With the arrival of further contamination data (3 PM), the commission gave the order to implement distribution with droppers or automatic pipettes of a saturated solution of KI, roughly on the basis of weight and the assumption that body iodide distribution and blocking efficiency were similar to that which has been found in adults. The following protocol was used: (1) 15 mg for newborns; (2) 50 mg for children 5 years or under; (3) 70 mg for all others; (4) Because the cancer risk for adults was believed to be low, and some side effects (e.g., in persons with nodular goiter) might be anticipated, iodide prophylaxis was not recommended for adults; (5) Iodide prophylaxis was recommended for pregnant and lactating women, but was not mandatory.

The mass media were used to announce the protective action and to appeal for volunteers to assist in the nationwide distribution (especially in villages).

The following additional protective measures were instituted by the commission:

(1) The feeding of cows on pastures or with fresh fodder was banned countrywide until May 15.

(2) Fresh milk with radioactivity above 1,000 Bq/L was banned for consumption by children and pregnant or lactating women.

(3) All children under the age of 4 were provided powdered milk through numerous distribution centers. Although the decision to substitute powdered milk was made on April 30, the fact that there was a holiday, and the fact that stores were closed on the weekend, delayed effective distribution until May 2.

TABLE I

Environmental Contamination Before and After the Chernobyl Accident*

| Source of Radiation | Units† | Before Accident (Mean) | April 28–May 13 (Maximal) | May 14 (Maximal) |
|---|---|---|---|---|
| External | mR/h | 0.012 | 0.43 | 0.028 |
| Air (β) | Bq/m$^3$ | 0.1 | 571 | 1.2 |
| Milk (β) | Bq/L | 42 | 2.000 | 220 |
| Water (β) | Bq/L | 0.4 | 111 | 5.0 |
| Grass (β) | Bq/kg | 223 | 105,000 | 18,200 |
| Vegetables (β) | Bq/kg | 132 | 253,800 | 5,600 |

*Mean of 12 provinces; taken from [7]. Total β radioactivity in air, milk, grass, and so forth, as well as external radiation, was measured over 24 hours in 208 monitoring stations localized countrywide.
†1 Ci = 3.7 × 10$^{10}$ Bq.

(4) Approximately 3,000 metric tons of powdered milk were available. Thereafter, powdered milk was imported mostly from Holland.

(5) Children and pregnant or lactating women were advised to eat a minimum of fresh leafy vegetables (until May 16).

A total of 10.5 million doses of KI were given to children and 7 million doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases. In addition, follow-up studies (to be detailed below) revealed that about 6% of the prophylaxis resulted from panic-driven, self-administered tincture of iodine before the KI program was initiated.

By May 3, air contamination had decreased about fourfold and there appeared to be no further radioiodine deposition on the ground; thus it was not considered necessary to distribute a second dose of KI. Direct thyroid radioiodine uptakes [7,13,19] obtained in Warsaw on May 5 showed that the intervention level for thyroid radioactivity in children under 16 was not exceeded as shown in Table II. This was not the case in children from areas of high contamination. Despite prophylactic measures, some children exceeded the 5,700-Bq intervention level on May 15 (Table II). Note that these measurements were made 10 days later than those in Warsaw. It is of interest that the Lomza values were in the same range as those in 34 Polish travelers who returned from Kiev between April 26 and May 5 and whose mean thyroid counts were 2,180, 4,471, and 2,125 Bq in children, women, and men, respectively [1]. It is concluded that some regions in Poland would have received (or did receive) enough $^{131}$I to exceed the intervention level for dose commitment in a substantial number of children. Due to the failure by the power station management to provide punctual notification of the accident, unprotected intake of $^{131}$I occurred that might have been substantially reduced.

The protection program consisted of two phases

TABLE II

Thyroid Radioiodide in Children and Adults in Warsaw and Lomza*

| | | No. Examined | Thyroid $^{131}I$ Content (Bq) Mean | Minimal | Maximal |
|---|---|---|---|---|---|
| Warsaw, May 5 | Children | 171 | 403 | 30 | 1,435 |
| | Women | 154 | 383 | 67 | 1,519 |
| | Men | 81 | 425 | 68 | 1,360 |
| Lomza, May 15 | Children | 13 | 4,668 | 1,012 | 14,098 |
| | Women | 16 | 3,907 | 980 | 17,770 |
| | Men | 7 | 3,441 | 878 | 10,219 |

*Modified from [7]. Thyroid $^{131}I$ was measured using two probes with 33 × 25-mm thallium-activated sodium iodide crystals each at 25° from the midline of the neck using the 361-keV photopeak. The device was calibrated with a plexiglass thyroid-neck phantom (150 × 150 mm) with a 32 × 52-mm hole for a standard $^{131}I$ solution. The calibration factor (cps/Bq) was determined at two geometries and was $5.87 \times 10^{-3}$ and $7.94 \times 10^{-3}$ for children and adults, respectively. Uncertainty due to placement in these factors was 20% at the 2 standard deviations confidence level. Counting time was 10 to 15 minutes and the lower limit of detection was 30 Bq in the thyroid. Subjects had their hair washed and neck wiped before counting. Between April 29 and June 27, 1,500 subjects were measured [13,19].

that had relatively little overlap in time. The first phase, initiated on the fourth day of the accident (i.e., April 29) and virtually completed by May 2, was the distribution of KI to greater than 90% of the children under the age of 16 and about a quarter of the adults. Because of diminishing air contamination, the KI prophylaxis was not repeated. In the second phase, ingestion of $^{131}I$ became the dominant source and powdered milk was made available to all children under 4 years of age. All milk with more than 1,000 Bq/L was banned. This program started effectively on May 3 and was associated with a warning to restrict leafy vegetables. Nevertheless, the main protective measures, KI administration and milk and vegetable withdrawal, effectively protected many children against radioiodine.

## PILOT STUDY

After the acute protective phase was terminated in June 1986, it became desirable to initiate a follow-up program with the following objectives:

(1) To obtain more reliable thyroid burden estimates for children and adults in different regions of Poland and to evaluate possible functional and morphologic effects of thyroid irradiation from the Chernobyl accident.

(2) To evaluate the degree of protection achieved during the acute phase, and to obtain accurate information on the incidence of side effects to the single dose of KI.

(3) To evaluate thyroid function of newborns exposed *in utero* and to assess KI effects on this population.

(4) To evaluate the effect of the single dose of KI on subjects with a previous history of thyroid disease.

(5) To obtain estimates of the incidence of adverse reactions to KI.

The program, denoted MZ-XVII, was divided into two phases. The first phase, lasting from October 1987 to December 1988, was intended to establish study populations and methods of study. Pilot studies were carried out with an initial number of 12,600 questionaires. Of these, only 6,082 (48%) persons responded satisfactorily. This was considered to be an inadequate degree of compliance and attempts were made to increase the fraction of responders. In some areas, we found that compliance was markedly improved only by examination and blood collection in the subjects' homes (see below). With these measures, total compliance was increased to 66%.

An epidemiologic software system was devised to provide uniform data collection and storage for the different study regions and to control implementation. A great deal of effort went into the training of personnel in order to obtain uniform medical and laboratory examinations and questionnaire handling. Assay kits were tested and selected for use in the various regional centers [20]. Quality control involved checking of assay kits, provision of standardized reference sera to be used in the five centers, and measurements of every 320th sample in Warsaw.

The study regions were selected on the basis of high, medium, and low estimated $^{131}I$ thyroid dose commitments and the presence of medical centers in such areas able to carry out population studies, preferably with previous epidemiologic experience in the thyroid field. This led to the selection of Bialystok and Krakow for the high-contamination regions, Poznan and Wroclaw as moderately contaminated regions, and Szczecin as an area nearly free of contamination.

The pilot study showed that the first questionnaire was too detailed and that certain questions could be deleted. This was also true for the medical examination form. These were therefore simplified. Analysis of the efficiency of the data entry into the computer system revealed that as much as 11% of the data from the questionaires and medical examinations was lost during this procedure. Therefore, the software was revised so as not to accept incomplete entries.

## FIELD STUDY

On statistical grounds, it was estimated that about 30,000 subjects would be needed for the follow-up study. To attain this goal, and because of the poor compliance in the pilot study, 52,092 persons were questioned and 34,491 completed the study. The compliance was 66.2%, and we attribute this increase to additional efforts to locate subjects in their homes. The group studied represented 0.09% of the total population of Poland; 32% of these lived in villages and 68% in towns—a distribution typical for Poland as a whole. The age and regional distribution for the study cohort is shown in Table III. Children to age 16 (12,641) accounted for 36.65% of the group, with 6,137 girls and 6,504 boys. Among the adults (20,578), there were 12,374 women and 8,204 men.

TABLE III

Distribution of Polish Population Investigated in Five Regions*

| Subjects | Bialystok | Krakow | Poznan | Wroclaw | Szczecin | Total |
|---|---|---|---|---|---|---|
| Children | | | | | | |
| 1–10 years | 2,825 | 1,255 | 2,018 | 825 | 1,603 | 8,526 |
| 11–16 years | 1,163 | 505 | 1,069 | 556 | 822 | 4,115 |
| Teenagers | | | | | | |
| 17–19 years | 294 | 186 | 460 | 202 | 130 | 1,272 |
| Adults | | | | | | |
| 20–40 years | 3,805 | 1,655 | 3,923 | 1,515 | 1,182 | 12,080 |
| >40 years | 1,938 | 1,138 | 3,390 | 1,212 | 820 | 8,498 |
| Total | 10,025 | 4,793 | 10,860 | 4,310 | 4,557 | 34,491 |

*Data taken from [1].

TABLE IV

Predicted Minimal and Maximal $^{131}$I Thyroid Committed Doses (mSv) in Poland*

| Age of Inhabitants | Contamination | | | | | |
|---|---|---|---|---|---|---|
| | High (12 Provinces) | | Average (23 Provinces) | | Low (14 Provinces) | |
| | Minimal | Maximal | Minimal | Maximal | Minimal | Maximal |
| <1 year old | 15.5 | 68.1 | 5.2 | 37.7 | 3.1 | 23.1 |
| <2–5 years | 11.3 | 40.8 | 6.3 | 22.4 | 3.8 | 13.7 |
| <6–10 years | 10.9 | 32.4 | 6.0 | 18.2 | 3.7 | 10.9 |
| Adults | 7.1 | 18.1 | 3.9 | 9.9 | | 6.1 |

*Data modified from [19].

TABLE V

Effect of the Time of KI Prophylaxis on the Committed $^{131}$I Dose to the Thyroid*

| Age | Date of KI | Inhalation Only | | | Inhalation + Ingestion | | |
|---|---|---|---|---|---|---|---|
| | | Bq | mSv | Reduction % | Bq | mSv | Reduction % |
| <1 year | None | 1,767 | 2.3 | 0 | 13,554 | 17.5 | 0 |
| | April 29 | 664 | 0.8 | 64 | 8,132 | 10.5 | 40 |
| | April 30 | 1,152 | 1.5 | 35 | 10.27 | 13.3 | 24 |
| | May 1 | 1,674 | 2.1 | 7 | 11,310 | 14.6 | 17 |
| 1–5 years | None | 4,550 | 2.9 | 0 | 16,537 | 10.4 | 0 |
| | April 29 | 1,665 | 1.0 | 63 | 10,573 | 6.6 | 36 |
| | April 30 | 2,981 | 1.9 | 24 | 12,335 | 7.7 | 25 |
| | May 1 | 4,247 | 2.7 | 7 | 14,187 | 8.9 | 14 |

*Data modified from [19].

Evaluation of the thyroid committed dose for $^{131}$I was done by the direct method [13,19] on the basis of measured thyroid $^{131}$I in 1,500 subjects that had been counted in the 5 study areas between April 29 and May 6 for the most part, with some counts up to May 19; and by an indirect method based on the 5-compartment model of iodine metabolism developed by Johnson [21], using measured $^{131}$I in air, milk, and other foods, standard values for inhalation rate and milk and food consumption, as well as parameters such as age, sex, thyroid size, and iodine uptakes (Table IV). For children under the age of 1 year, the projected mean maximal burden would have exceeded 50 mSv in 12 provinces, with a range of 53.3 to 87.5 mSv. There were a number of "hot spots" in each of the areas wherein the thyroid burden was approximately 6 to 10 times that in the surrounding areas. For children 1 to 5 years old, only one province showed a predicted mean maximal burden in excess of 50 mSv with a range of 47.6 to 55.8 mSv. In none of the older children or adults was the mean maximal burden in excess of this limit, although the spread was considerable and some individuals exceeded the limit.

Anatomic changes in the thyroid were few up to 4 years after the accident. Two children were found to have benign nodules but no childhood thyroid cancers

TABLE VI

Contribution of KI and Powdered Milk to Reduction of Thyroid Burden*

| Date of KI Prophylaxis | Dose Reduction Due to KI (%) | Dose Reduction From Milk† and Vegetables (%) | Total Dose Reduction (%) |
|---|---|---|---|
| April 29 | 40 | 30 | 70 |
| April 30 | 25 | 30 | 55 |
| May 1 | 12 | 30 | 42 |
| May 2 | 8 | 30 | 38 |

*Data are from 11 provinces with higher exposure [7,19].
†Calculated on the assumption that only powdered milk was used and that vegetables were avoided. In children less than 1 year of age, there is an uncertainty as to the contribution of unprotected breast feeding to the thyroid burden.

TABLE VII

Effects of KI Prophylaxis on $^{131}$I Thyroid Committed Dose in Children From Warsaw and Ostroleka Province*

| No. | Prophylaxis (Date) | Average Dose (mSv) | Range (mSv) | % Dose Reduction |
|---|---|---|---|---|
| A | | | | |
| 7 | None | 6.3 ± 4.9 | 4.8–29 | None |
| 18 | Yes (April 29) | 3.4 ± 3.1 | 1.7–13.1 | 45 |
| 67 | Yes (April 30) | 7.0 ± 4.0 | 1.5–1.9 | 41 |
| B | | | | |
| 7 | None | 107 | 82–133 | None |
| 18† | Yes (April 30) | 63 ± 6.9 | 11–218 | 45 |
| 13‡ | Yes (April 30) | 31 ± 14 | 13–54 | 41 |

A = Warsaw (average contamination); B = Ostroleka Province (high contamination).
*Data modified from [13]. Method as in regard to Table I.
†In villages.
‡In towns.

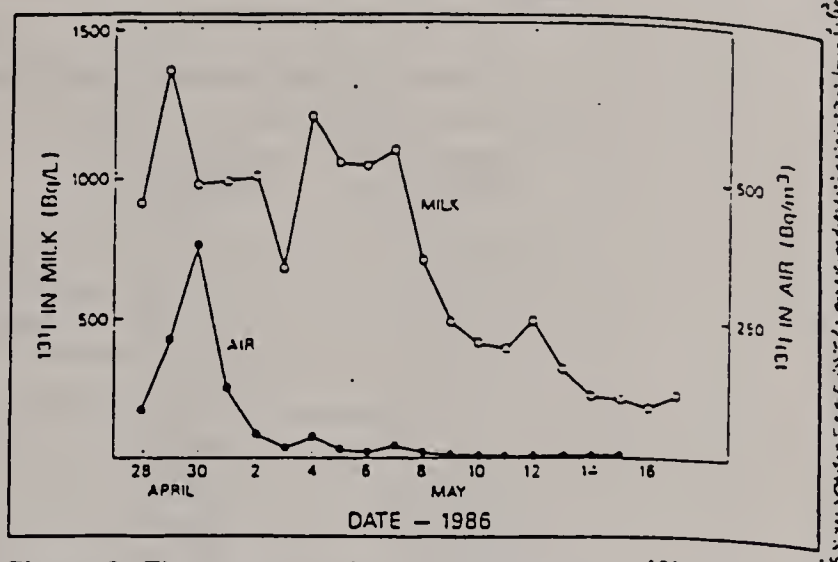


Figure 1. Time course of contamination with $^{131}$I in Poland following the Chernobyl accident. $^{131}$I in milk was counted twice daily (AM and PM) in 9 milk processing plants in pooled samples from 21 provinces. $^{131}$I in air was counted every 6 hours in 49 provinces.

were found in the study population. It is, of course, too early to make definitive statements regarding thyroid neoplasms and a long-term follow-up study is planned. Comparison of total and nodular goiter prevalence several years before and after the accident showed no significant difference.

## PROPHYLAXIS

Approximately 18 million doses of KI solution were distributed primarily, but not exclusively, to children. The bulk of the distribution took about 3 days, with the residual distribution completed on the fourth day, that is, from April 29 to May 2. In certain areas, e.g., Bialystok, about 75% of the population was reached on the first day, but in other areas the bulk of the distribution occurred on the next 2 days. Eventually, 95.3% of children received iodide prophylaxis; 86.7% took a single dose, 2.39% took two or more doses, and a surprising 6.14% were given diluted tincture of iodine by their parents before the start of the program and then took a single dose of KI [1]. This was confirmed by the brisk increase in sales of tincture of iodine in pharmacies. Although not advised to take KI, 23.2% of adults took iodine prophylaxis (19.6% took a single dose of KI, 1.03% two or more doses of KI, and 2.61% took tincture of iodine before the start of the program). This translates to approximately 10.5 million children 16 years old and under, and approximately 7 million adults who received iodide prophylaxis.

The degree of protection afforded children 1 to 5 years of age by the single dose of KI given on different days calculated by the five-compartment model is compared with a comparable total thyroid $^{131}$I reconstructed dose commitment for an unprotected population in Table V. It is clear that *early* KI administration is, as expected, more effective, and that a single dose of KI will not offer long-term protection against repeated dietary $^{131}$I intakes. Had there been prompt warning from the Russian authorites, the 24- or 48-hour gain in time might have provided an extrapolated protection of 53% and 67%, respectively. On the other hand, at later intervals, most of the contamination and hence, potential protection, is related to ingestion. The calculated thyroid $^{131}$I dose commitment if all protective measures would have been withheld is also listed in Table V. It is clear that the bulk of the later $^{131}$I burden derives from ingested sources (Table V and Table VI).

Milk radioactivity varied widely from day to day as shown in Figure 1, but as expected, remained elevated long after contamination of the air had subsided. The irregularity in the milk contamination may be partly explained by variable proportions of milk from different regions entering the milk pool that was sampled each day. As shown in Table I, individual maxima often were found to exceed the limit of 1,000 Bq/L by April 30, and it became necessary to supply powdered milk to children. After May 7, the milk radioactivity values progressively declined (Figure 1) and it was judged safe to terminate the powdered milk program on May 16. Together with the restriction of leafy vegetables, the calculated reduction of thyroid burden by food restriction provided an additional 30%

reduction in thyroid committed dose on the assumption of full compliance with the program [13]. The average total reduction in thyroid burden in three fourths of the children (aged 1 to 4) in the 11 provinces treated between April 29 and May 2 was 62%, whereas the remaining fourth of the children received only an average of 40% reduction. As a result of the protective measures, about 90% of children up to the age of 16 had their dose commitment kept below 50 mSv. Both Tables V and VI reemphasize the need for rapid intervention with KI in order to achieve the desired level of protection. Considerable additional protection might have been achieved with early warning. Validation of the reconstructed thyroid burdens was possible from data obtained by direct thyroid measurements in children up to 5 years of age. These are shown for an area of average contamination (Warsaw) and for a heavily contaminated region (Ostroleka) in Table VII [19]. All data for thyroid dose were consistent with a lognormal distribution. It is apparent that the degree of protection calculated from such measurements is similar to those derived from dose reconstruction. The overall conclusion, based on both direct and reconstructed dosimetry, is that KI prophylaxis amounted to 40%, 25%, and 12% on April 29 and 30, and May 1, respectively, of the total committed dose to May 30 [22,23].

## SIDE EFFECTS OF A SINGLE DOSE OF KI

### Intrathyroidal

Quantitative aspects of adverse reactions to iodide have been hampered in the past by the small size of the study groups, selection bias, anecdotal reports, use of very large doses of KI, or limited follow-up [24–26]. One of the chief aims of the field study was an evaluation of the intrathyroidal and extrathyroidal side effects after a known intake of KI in a large population. Some 95% of children received KI [1]. Of 12,084 children in the study group who received KI, 91.4% had normal serum thyroid-stimulating hormone (TSH) levels measured during 1989 to 1990 (mean 1.5 mIU/L) (normal range 0.3 to 3.8 mIU/L), 4.7% had lower TSH values (mean = 0.19 mIU/L), and 3.9% had values in excess of 3.9 mIU/L (mean = 5.7 mIU/L). This should be compared with the values from 557 unprotected children of the same age distribution: 93.1% normal, 3.7% low, and 3.2% high (the respective means are 1.5, 0.2, and 5.1 mIU/L). There are no statistical differences between the protected and unprotected groups. Thus, until 1989, no permanent effect on thyroid function could be detected by this test. These conclusions are confirmed by screening studies for congenital hypothyroidism in Central Poland on 120,000 to 140,000 newborns for the years 1985, 1986, and 1987 [27,28]. The incidence of transiently elevated TSH levels and of confirmed congenital hypothyroidism remained unchanged. Serum levels of thyroxine ($T_4$), triiodothyronine ($T_3$), and antithyroid antibodies in these children showed a similar lack of difference between the protected and unprotected groups [20]. Thus, we found no readily detectable long-term disturbance in thyroid function as a result of a single dose of KI in children. Similar conclusions were reached from a study carried out in 1989 of 3,363 women and 1,688 men without previous thyroid disease who had received KI, whose serum $T_4$, $T_3$, TSH, and antibody levels were not different from those in 9,344 women and 7,225 men not receiving iodide prophylaxis [1,20].

TABLE VIII

Prevalence of Thyroid Disorders Before and After KI Prophylaxis*

| Diagnosis | Without Prophylaxis (1,282 Patients) (%) | With KI Prophylaxis (774 Patients†) (%) |
|---|---|---|
| Nontoxic diffuse goiter | 429 (33) | 384 (49) |
| Nontoxic nodular goiter | 432 (34) | 255 (33) |
| Graves' disease | 124 (9.7) | 32 (4.1) |
| Toxic nodular goiter | 121 (9.4) | 34 (4.4) |
| Hypothyroidism | 44 (3.4) | 27 (3.5) |
| Post-thyroidectomy | 129 (10) | 40 (5.2) |
| Thyroid cancer | 3 (0.23) | 2 (0.26) |

*From the Lodz Outpatient Endocrine Clinic [29]. All diagnoses were made before 1986. The course of the disease was ascertained by questionnaire, clinic visits, laboratory tests for $T_4$, $T_3$, TSH, and antibodies, and ultrasound scans. Thirty-two patients had side effects with a distribution like that of Table X. Five of these patients consulted a physician.
†Sixty-nine of these patients took more than one dose of KI.

Of 2,521 adults with thyroid disease diagnosed and/or treated before 1986 at the Lodz Clinic [29], a single dose of iodine was taken by 705 patients, and 69 took 2 or more doses. On the other hand, 1,282 did not receive KI. The diagnoses in the treated and untreated groups are listed in Table VIII. Although the distribution in the two groups is not identical, their subsequent clinical courses between 1986 and 1990 were identical irrespective of iodide prophylaxis. In none of the patients with nodular goiter was there a single case of induction of thyrotoxicosis, nor was there any exacerbation of preexisting hyperthyroidism or a change in antibody titers or prevalence in patients with Graves' disease.

Acute, thyroid-related reactions were, however, seen in 0.37% of newborns who received KI prophylaxis on the second day of life. Despite the fact that these infants received up to 5 times the mg KI/kg body weight that adults received, only 12 of 3,214 infants showed a transient increase in serum TSH levels and had decreases in their serum free $T_4$ (Table IX). This transient thyroid inhibition has had no known sequelae to date, but these findings point to the need for careful observation in case more prolonged periods of iodide prophylaxis are required.

TABLE IX

Intrathyroidal Side Effects Seen in Newborns After KI Administration During the First Days of Life*

| Time of Examination | 3rd–5th Day of Life | 16th–20th Day of Life |
|---|---|---|
| No. of examined | 3,214 | 3,214 |
| No. (%) with elevated serum TSH | 12 (0.37) | None |
| Mean serum TSH (mIU/L) | 83.5 ± 35.2 | 6.4 ± 2.3 |
| No. (%) with decreased serum free $T_4$ | 12 (0.37) | None |
| Mean serum free $T_4$ (nmol/L) | 126.0 ± 9.4 | 116.1 ± 19.6 |

*Modified [28]. Normal range of serum TSH (very young children) 2.5–11.0 mIU/L. Normal range of serum free $T_4$ (very young children) 90.1–153.0 nmol/L.

TABLE X

Extrathyroidal Side Effects After KI Prophylaxis*

| Symptoms | Children No. | Children % | Adults No. | Adults % |
|---|---|---|---|---|
| None | 11,482 | 95.4 | 4,833 | 95.5 |
| Iodine mumps | 0 | | 0 | |
| Parotitis | 0 | | 0 | |
| Headache | 22 | 0.18 | 35 | 0.69 |
| Stomachache | 43 | 0.36 | 32 | 0.63 |
| Diarrhea | 23 | 0.19 | 6 | 0.12 |
| Vomiting | 286 | 2.38 | 43 | 0.85 |
| Shortness of breath | 13 | 0.11 | 32 | 0.63 |
| Skin rashes | 129 | 1.07 | 63 | 1.24 |
| Others | 42 | 0.35 | 10 | 0.20 |
| Total taking prophylaxis | 12,040 | | 5,061 | |

*Data modified from [1]. Includes patients who took one or multiple doses of KI or tincture of iodine.

No controls available → meds vs panic reaction

This caution also applies to KI administration to women in the second half of pregnancy. In addition, there were four cases of thyroid pain in adults (0.08%) and none in children. These subsided spontaneously and were not followed up to ascertain the possibility of iodide-induced thyroiditis.

The thyroid status of children born in 1986 and examined in the second to third year of life was compared with that in an age- and sex-matched group born in 1987, when radioiodine was long gone from the environment. No significant differences existed between these two groups [27].

### Extrathyroidal

Nonthyroidal side effects of KI occurred after a very small fraction of the total number of doses administered; they were, nevertheless, somewhat more common than expected (Table X). Vomiting was the most common. It is not clear to what extent this was due to maladroitness in the administration of KI. We were alerted to this possibility by the finding that those children receiving diluted tincture of iodine had about twice the incidence of vomiting as the remainder of the group. Similarly, a few cases of diarrhea and gastric complaints were noted in both children and adults, but it remains unclear to what extent this can be related to the iodide administered. There were no complaints of iodide mumps occasionally described in the literature after single-dose iodide administration. Skin rashes were reported in a surprising number—approximately 1%—of both children and adults. These were of a minor nature and there is no record that a dermatologist was consulted in any of them. A number of subjects with adverse reactions (18% of children and 22% of adults) consulted a physician for these reactions. In turn, approximately 80% of these visits were judged not to require further medical attention; thus it can be estimated that about 4% of all adverse reactions reported were medically significant. It should be pointed out that control values for these side effects in a population not receiving KI are not available. Also, the relation of some of these complications to iodide rather than to the panic conditions is uncertain at present. Nevertheless, we suggest an estimate of approximately 0.2% of the population studied had medically significant adverse reactions to KI. Two adults with chronic obstructive lung disease and known sensitivity to iodides nevertheless took KI out of fear of radiation and promptly developed acute respiratory distress that required hospitalization. This was not seen in any of the other patients.

## COMMENTS

A number of studies have shown unambiguously that radioiodine uptake (burden) can be effectively blocked by KI administration provided this occurs before or within a few hours of exposure to the isotope [11,23,24,30,31]. The extent of protection and its duration are dose-related but even a large single dose (i.e., greater than 100 mg $I^-$/d) will not protect for much longer than approximately 36 hours. On the other hand, continuing radioiodine contamination could still be protected against, and the ability to respond as quickly as 24 to 48 hours after the decision to intervene had been made testifies to the value of well-organized pharmacy and distribution systems. In many other countries, such centralization does not exist, which emphasizes once again the need for storage of KI tablets in various critical locations that can demonstrably provide rapid distribution in case of an accident. During actual accident conditions, radioiodine contamination is likely to occur over extended periods, as was the case in Poland after the Chernobyl accident. Thus, even delayed KI prophylaxis will provide partial protection—the extent depending on the nature of the exposure versus time curve.

Many children under the age of 1 year in the 12 provinces would have received greater than 50 mSv in the absence of any protective measures. The calculated thyroid burden in some children up to 5 years of age also exceeded this limit. The protective measures of a single dose of KI and milk substitution lowered the burden to less than 50 mSv in most of the children at risk. The effective reduction in thyroid burden amounted to approximately 40%; this might have been increased to 60% to 70% with earlier prophylaxis, particularly with respect to inhaled $^{131}I$. Continuing high levels of contamination would, of course, mandate repeated KI distribution.

The present program involved the largest population ever studied after a single pharmacologic dose of KI. Of the approximately 34,000 respondents to the questionnaire, 12,040 of 12,641 children received iodides, and 5,061 of the adults took iodides. No acute intrathyroidal sequelae were seen except for the transient thyroid blockade in newborn infants. Moreover, in adults with thyroid disease diagnosed before 1986, the 4-year follow-up showed the course of these disorders not to be affected by KI prophylaxis. There were a surprising number of mild gastrointestinal disorders both in children and in adults. The available literature [24,26], although very incomplete, does not reveal this to be a problem at the KI doses used. The bulk of these gastrointestinal complaints did not require medical attention, and we are uncertain at present whether they were due to psychologic factors, inept methods of KI administration, or intrinsic toxicity. We suspect that the number of these reactions would have been substantially reduced if KI had been available in tablet form. It should also be mentioned that in case of difficulties with the administration of KI to infants or children, there have been good results with syrup of hydriodic acid [32]. Similar uncertainties apply to some of the other side effects listed in Table X, but the approximately 1% skin rashes must be considered significant. There were no serious adverse reactions among the approximately 18 million doses of KI given except for the two adults with known iodide sensitivity who had severe reactions following KI; this serves as a warning that such patients must be identified, educated about their sensitivity, and excluded during prophylactic programs of this sort. Finally, the incidence of medically significant, but not serious, reactions to this single dose of KI was low enough (0.2%) to make us believe the KI distribution was the correct and safe response.

The response to a widespread accident like the Chernobyl "meltdown" is as much a social problem as a medical or scientific one. It requires rapid organization of large numbers of people and facilities, and for this the highly centralized structure of the Polish government of the time was very suitable. This is exemplified by the prompt mobilization of local health centers and volunteers, the efficient preparation and distribution of KI through a centralized pharmacy system, a nationalized powdered milk system, and so forth. This permitted the rapid initiation of response measures that likely would have taken substantially longer in less centralized systems. Since speed is of the essence, it follows that a well-planned emergency response and protective mechanism must be in place *before* an accident occurs and preferably tested by some sort of mock alert. This involves a protocol for dosimetry including an agreement on the intervention level, arrangements for evacuation in near-field regions, and storage of readily available KI (probably in a number of places in a large country). We believe that current shelf-life estimates for KI are underestimates, and that with suitable protection from light and moisture (i.e., foil-wrapped), shelf life can be extended for many years. Furthermore, a loss of 20% from a tablet of 130-mg KI will leave sufficient iodide for adequate protection. This is an argument for providing somewhat greater than minimal KI doses [31]. Another argument is the longer duration of protection after a larger KI tablet in case of a missed dose. Equally important is the identification of supplies of uncontaminated foods and milk, and, perhaps most important of all, a decision as to who will be in charge.

In addition to the above recommendations, the present study brought to light some tactical suggestions for future investigations.

(1) Compliance with questionnaires requires active supervision.

(2) Compliance with a powdered milk program is hard to evaluate in rural communities with their own milk supplies.

(3) Pregnant and lactating women will have to be vigorously recruited for programs designed to prevent $^{131}I$ ingestion.

(4) Dosimetry standards and equipment must be in place before accidents and should be available in several centers or in mobile units.

(5) Data required for dose reconstruction should be collected at the time of the accident to the extent possible, especially where direct measurement capability is limited. Obviously, as many direct thyroid radioactivity measurements as possible are desirable, but certainly enough such measurements should be available to validate dose reconstructions. "Hot spots" should be identified wherever possible to avoid skewing of exposure data.

(6) Control values for some of the side effects were not available for the present study and should (ideally) be sought during a panic situation of a different sort where KI is not involved. Moreover, control values for goiter and thyroid tumor prevalence within a national registry are indispensable for any subsequent evaluation of radiation effects.

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P.C.M.I.T JUNE 27, 1996

# The Need for a Stockpile of Potassium-Iodide for Public Use in Case of a Major Release of Radioactive Iodine from a Reactor Accident

Frank von Hippel

(Presentation before an ad hoc Subcommittee on Potassium Iodide of the Federal Radiological Preparedness Coordinating Committee, Federal Emergency Management Agency, Room 401, 500 C St., SW, Washington, D.C., June 27, 1996, 11:30 AM)

**Background** (see also vita attached). I was trained as a nuclear physicist. I am currently a Professor of Public and International Affairs at Princeton University. During the 16-month period, September, 1993 through 1994, I was Assistant Director for National Security in the White House Office of Science and Technology Policy. I am currently the chairman of the research arm of the Federation of American Physics.

**Relevant Publications.** With regard to the subject of this session, I have been involved with the potassium-iodide (KI) issue since 1974-75, when I led the subcommittee on containment and consequence mitigation of the American Physical Society's (APS) Study Group on Light Water Reactor Safety. In 1979, after the Three Mile Island accident, I draw attention to the Study's recommendation that KI be stockpiled for thyroid blocking with a letter to the editor of *Science* magazine and a short piece in the *IEEE Spectrum*.[1] I wrote an article about the NRC's staff's resistance to this recommendation in the October 1980 issue of the *Bulletin of Atomic Scientists* [2] and was invited to brief the NRC on my views a month later.[3] In 1982, with Jan Beyea, I completed a report requested by the President's Council on Environmental Quality on what the consequences might have been had the containment at Three Mile Island failed.[4] Our findings and our recommendations concerning thyroid protection and containment improvement are summarized in an article in *The Bulletin of the Atomic Scientists*.[5] Then I went on to other things, except that, after the Chernobyl accident, at the request of a *New York Times* reporter, Tom Cochran and I made estimates of the consequences and determined that largest number of injuires by far would be thyroid tumors and cancers. These estimates were subsequently published in the *Bulletin of the Atomic Scientists*. [6] The three articles in the *Bulletin of Atomic Scientists* were reprinted in a collection of my writings published by the American Institute of Physics in its Masters of Modern Physics series.[7] I am submitting a copy of that book along with my statement.

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[1] Frank von Hippel, "Available Thyroid Protection," letter to the editor, *Science 204*, June 8, 1979, p. 1032 [See also the subsequent debate with Rosalyn Yalow: "Potassium Iodide Policy," letter to the editor, *Science 218*, October 1, 1982, p. 6; "Potassium Iodide for Thyroid Protection," letter to the editor, *Science 218*, December 17, 1982, p. 1174; "Thyroid Protection," letter to the editor, *Science 221*, 2 September 1983, p. 906]; "Mitigating the Effects of Nuclear Accident[s]," *IEEE Spectrum*, Nov. 1979, p. 79.

[2] "The NRC and Thyroid Protection - One Excuse After Another," *Bulletin of the Atomic Scientists 36* (October 1980), pp. 44-46, reprinted in *Citizen Scientist*.

[3] "The NRC Decision-Making Process Concerning Thyroid Protection," Invited Briefing to the Nuclear Regulatory Commission, November 18, 1980.

[4] *Some Long-Term Consequences of Hypothetical Major Releases of Radioactivity to the Atmosphere from Three Mile Island: Report to the President's Council on Environmental Quality* (with J. Beyea). Princeton University, Center for Energy and Environmental Studies Report # PU/CEES 109, 1980, 94 pp.

[5] "Containment of a Reactor Melt-Down" (with J. Beyea), *Bulletin of the Atomic Scientists*, September 1982, pp. 52-59, reprinted in *Citizen Scientist*.

[6] "Chernobyl, The Emerging Story: Estimating Long-Term Health Effects" (with Thomas B. Cochran), *Bulletin of the Atomic Scientists*, August/September 1986, pp. 18-24. See also, letter to the editor, November 1986, pp. 55-56, reprinted in *Citizen Scientist*.

[7] Frank von Hippel, *Citizen Scientist* (American Institute of Physics, 1991).

**The Issue.** This session is a result of a petition to the NRC (F.R. 60, #227; November, 27, 1995, pp. 58256-9) in which Peter G. Crane has requested that the Federal government assure the availability of potassium iodide (KI) and guidance for its use to the states.

**The Recommendation of the American Physical Society Study Group on Light Water Reactor Safety.** This subject has been a concern of mine since 1974, when I led the subcommittee on containment and consequence mitigation of the American Physical Society's (APS) Study Group on Light Water Reactor Safety. One of our major recommendations was that

> "a national policy of stockpiling thyroid-blocking chemicals for possible emergency distribution should be established."[8]

We were impressed by the following facts:

i) In case of a melt-down accident and breach of containment, the ability of the thyroid to concentrate inhaled radioiodine could result in large (tens to hundreds of rads) thyroid inhalation doses more than 100 miles downwind and over areas much too large to be evacuated;[9]

ii) A 100-rad X-ray dose to a child's thyroid brings with it a few-percent risk of benign and malignant thyroid tumors during the next 30 years;[10] and

iii) A relatively safe and inexpensive thyroid-blocking chemical was available in the form of potassium iodide (KI).

**The First FDA Recommendation.** In 1978, the FDA concluded, following a risk-benefit assessment, that the drug was[11]

> "safe and effective for use as a thyroid-blocking agent in a radiation emergency under certain specified conditions of use because it has been widely used for many years in large doses, and on a long-term basis with an incidence of side effects and toxicities, in general, proportional directly to dose and duration of therapy [and] is suitable for OTC [over-the-counter] sale" in the small doses which would be used for thyroid blocking. The FDA requested submission of New Drug Applications for KI for use as a blocking agent in a radiation emergency.

**The Three Mile Island Near Miss.** During the 1979 Three Mile Island accident, I brought to the attention of the White House the importance of having KI available in case of a

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[8] Report to the American Physical Society by the Study Group on Light Water Reactor Safety (R.J. Budnitz, A.W. Castleman, D.E. Dorfan, F.C. Finlayson, R.L. Garwin, L.C. Hebel, S.M. Keeny Jr., H.W. Lewis, R.A. Muller, G.F. Smoot, T.B. Taylor and Frank von Hippel), *Reviews of Modern Physics 47*, Supplement 1, Summer 1975. p. S-109.

[9] Subsequently D.C. Aldrich, P. McGrath and N.C. Rasmussen calculated *adult* thyroid doses of 130 and 30 rems respectively, at distances 90 and 160 miles downwind from a large release of radioactive iodines from a reactor accident. Thyroid doses to children would by two to five times higher [*Examination of Offsite Radiological Emergency Protective Measures for Nuclear Reactor Accidents Involving Core Melt*, (Nuclear Regulatory Commission, NUREG CR-1130, 1978)].

[10] L.H. Hempelmann and others, *J. Natl. Cancer Inst. 55* (1975), p. 519.

[11] Food and Drug Administration, "Accidental Radioactive Contamination of Human Foods and Animal Feeds and Potassium Iodide as a Thyroid-Blocking agent in a Radiation Emergency," *Federal Register* (43FR 58790), December 15, 1978.

large release of radioiodine. The FDA subsequently arranged for its emergency manufacture and delivery to Harrisburg.[12] If a large release of radioiodine had occurred, it would probably have occurred before the arrival of the KI.[13] Fortunately, there was no large release of radioactivity to the atmosphere from the TMI accident because the containment held. However, the ice-condenser containments used at some other U.S. power reactors might not have withstood the pressure increase that resulted from the hydrogen fire in the TMI containment.[14]

**The Kemeny Commission Recomendation.** Subsequently, the President's Commission on the Three-Mile Island Accident (the Kemeny Commission) included KI stockpiling among its recommendations:[15]

> "For over 25 years, the use of blocking agents such as potassium iodide to prevent the accumulation of radioiodine in the thyroid gland has been known. The effectiveness of potassium iodide administration for thyroid gland protection in the event of releases of radioiodine was recognized by the National Council on Radiation Protection and Measurement in 1977. The Food and Drug Administration authorized use of potassium iodide as a thyroid-blocking agent for the general public in December 1978. However, at the time of the TMI accident, potassium iodide for this use was not commercially available in the United States in quantities sufficient for the population within a 20-mile radius of TMI..."(Findings, pp. 41-42)
>
> "An adequate supply of the radiation protective (thyroid blocking) agent, potassium iodide for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency." (Recommendations, p. 75).

However, the nuclear industry and the NRC staff continued to oppose this recommendation, and some members of the health-physics community argued that the long-duration, low-energy beta-radiation from I-131 decay would be much less damaging than the higher-energy betas from the shorter-lived iodine isotopes or from X-rays -- both of which had been found to cause thyroid tumors.[16]

**The Second FDA Recommendation.** In 1982, the FDA decided that it would be imprudent to accept these arguments and announced that[17]

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[12] Robert Reinhold, "Frantic Team Effort Provided Vital Chemical for Endangered Area," *New York Times*, April 4, 1979, A16.

[13] The event which most threatened the integrity of the containment occurred on March 28, ten hours after the beginning of the accident, when there was a hydrogen burn in the containment which raised its internal pressure by about 28 psi (*Report of the President's Commission on the Accident at Three Mile Island* (staff reports), II, p. 12]. The KI arrived in Harrisburg approximately three days later.

[14] An estimated 44-63 percent of the 22,600 kg of zirconium in the core of Three Mile Island Unit No. 1 was oxydized during the accident there [*Report of the Preseident's Commission on the Accident at Three Mile Island* (staff reports), II, p. 14]. In a September 8, 1980 letter to the NRC on the design of Sequoyah Nuclear Power Plants, Units 1 and 2 (which are equipped with ice-condenser containments), the NRC's Advisory Committee on Reactor Safeguards pointed out that, "For events involving more than 30 percent oxidation of the zirconium, hydrogen control measures may be necessary to avoid containment failure."

[15] *Report of the President's Commission on the Accident at Three Mile Island: The Need for Chaange, The Legacy of TMI* (October 1979).

[16] For a recent summary of these arguments, see U.N. Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation, 1994*, pp. 60-65.

[17] Food and Drug Administration, "Potassium Iodide as a Thyroid-blocking Agent in a Radiation Emergency: Final Recommendations on Use," *Federal Register 47*, June 29, 1982, pp. 28158-9.

> "FDA concludes...that risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem."

**The Chernobyl Experience.** In 1986, during the Chernobyl accident, I brought the urgency of KI distribution to the attention of Evgeny Velikhov, then Gorbachev's informal science advisor. Subsequently, in response to a request by a *New York Times* reporter, Thomas Cochran and I estimated that 2,000-40,000 thyroid tumor cases (benign and malignant) would result from I-131 inhalation in the absence of thyroid blocking.[18] Unfortunately, the subsequent epidemic of thyroid tumors among children in Belarus and Ukraine has confirmed our rejection of the argument that the beta-radiation from I-131 is relatively benign.[19]

**FEMA Decision on Stockpiling Overdue.** It is 21 years since the American Physical Society Study Group on Light Water Reactor Safety made its recommendation to the NRC that KI be stockpiled. To my knowledge, no argument that has been brought forward in opposition to stockpiling of KI has withstood either peer review or the test of time while the arguments for stockpiling have become stronger with time. It is 17 years since the near miss at Three Mile Island, when potassium iodide was not available. We now have stark evidence from Chernobyl of the catastrophic health impacts of a large release of radioiodine from a reactor accident.

We have been lucky that there has been no major accidental release of radioiodine in the U.S. to the atmosphere during this prolonged debate. However, it would be tempting fate to assume that this luck will continue indefinitely. I urge FEMA to take advantage of the opportunity that Peter Crane has given you to revisit this issue and make the right decision before it is too late.

**Next Decision: Where to Stockpile?** I would also point out that a decision to stockpile will not be enough. It will be necessary to devise a strategy that will assure that as large a the fraction of the population at risk as practicable will have easy access to KI if needed -- especially children, as the most vulnerable segment of the population. Once FEMA has made the decision to assure the availability of KI, I would recommend that FEMA organize a study on the question of where to stockpile and how to arrange distribution if needed. Then you should have another hearing to get public reactions to the results of this study.

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18 "Chernobyl: Estimating the Long-term Health Risks".

19 Michael Balter, "Children Become the First Victims of Fallout," *Science* 272 (April 19, 1996), pp. 357-60.

## Frank von Hippel -- Biographical Data

Frank von Hippel, a theoretical physicist, is a Professor of Public and International Affairs at Princeton University and co-principal investigator with Harold Feiveson of Princeton's Program on Nuclear Policy Alternatives. From September 1993 through 1994, he was on leave as Assistant Director for National Security in the White House Office of Science and Technology Policy, and played a major role in developing U.S.-Russian cooperative programs to increase the security of Russian nuclear-weapons materials. Prior to September 1993 and since January 1995, he has served as chairman of the research arm of the Federation of American Scientists (FAS) where he directs a non-governmental U.S.-Soviet/Russian cooperative research project on the technical basis for new arms-control initiatives. He also chairs the editorial board of *Science & Global Security* and is a member of that of editorial board of the *Bulletin of the Atomic Scientists*.

von Hippel received his B.S. degree in physics from MIT in 1959 and D.Phil. in theoretical physics in 1962 from Oxford, where he was a Rhodes Scholar. During the following ten years, while his research focus was in theoretical elementary-particle physics, he held research positions at the University of Chicago, Cornell University and Argonne National Laboratory and served on the physics faculty of Stanford University.

In 1974, von Hippel's interests shifted to "public-policy physics." After spending a year as a Resident Fellow at the National Academy of Science, during which time he organized the American Physical Society's Study on Light-water Reactor Safety, he was invited to join the research and in 1984 the teaching faculty of Princeton University.

During the late 1970's, von Hippel's research focused on technical questions relating to the containment and mitigation of nuclear-reactor accidents, alternatives to recycling plutonium in nuclear-reactor fuel, and the potential for major improvements in automobile fuel economy. Since the early 1980's his research has focused on developing the analytical basis for: deep cuts in the U.S. and Soviet/Russian nuclear stockpiles, verified nuclear-warhead elimination, a universal cutoff of the production of unsafeguarded fissile materials and a comprehensive nuclear-warhead test ban.

von Hippel has served on advisory panels to the Congressional Office of Technology Assessment, U.S. Department of Energy, National Science Foundation and U.S. Nuclear Regulatory Commission and on the Boards of Directors of the American Association for the Advancement of Science, Federation of American Scientists (chairman) and Bulletin of the Atomic Scientists.

In 1977, von Hippel shared with Joel Primack the American Physical Society's 1977 Forum Award for Promoting the Understanding of the Relationship of Physics and Society for their book, *Advice and Dissent: Scientists in the Political Arena*. In 1989, he was awarded the Federation of American Scientists' Public Service Award for serving as a "role model for the public interest scientist." In 1991, the American Institute of Physics published a volume of von Hippel's selected works under the title, *Citizen Scientist* as one of the first three books in its "Masters of Physics" series. In 1993 he was awarded a 5-year MacArthur Prize Fellowship. In 1994, he received the American Association for the Advancement of Sciences' Hilliard Roderick Prize for excellence in Science, Arms Control and International Security. He is a member of the Council on Foreign Relations and on the Board of Directors of the Arms Control Association. (6/96)

# PUBLIC HEALTH IMPLICATIONS OF IODINE PROPHYLAXIS IN RADIOLOGICAL EMERGENCIES

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## Abstract

The increase in childhood thyroid cancer around Chernobyl indicates that significant thyroid doses occurred from radioiodine uptake at distances of several hundred kilometres from the accident site. Dose reconstruction suggests the bulk of iodine uptake resulted from ingestion of contaminated milk and leafy vegetables. The sensitivity to both external radiation and radioiodine in small children is high. Experience from Poland where iodine was taken by ten and a half million children and seven million adults in the aftermath of the accident, shows that the side effects of administration can be ignored. The maximum public health benefit is obtained by taking the tablets before exposure or as soon as possible afterwards, particularly if a rapid release occurs. Late administration has little health value to protect against inhaled or ingested radioiodine. In this situation the control of the supply of foodstuffs is the preferred intervention, but if this is not possible then iodine prophylaxis is essential. The protective effect of stable iodine needs to be ranked against other interventions such as shelter, evacuation and particularly the control of contaminated foodstuffs.

## Introduction

Radioactive iodine released to the environment after a reactor plant accident poses a health threat to those exposed due to its affinity for the thyroid gland and the effective transmission to individuals through the food chain, primarily in fresh cows' milk. The principal hazard to the public is from inhalation in the plume or ingestion of contaminated foodstuffs. One potent specific method exists to protect the thyroid gland from excessive uptake of radioiodine and this is rapid prophylaxis with stable iodine (as a tablet or fluid). Ideally this should be taken before the release occurs. This may be possible where the release occurs after a warning period. In catastrophic accidents

occurring without warning, such as the Chernobyl accident, this is not feasible. Measurements of activity in the thyroids of those close to the Chernobyl accident (Goulko) and the increased incidence of childhood thyroid cancer indicates that significant thyroid doses occurred from radioiodine uptake, principally iodine - 131 ($^{131}$I), at distances of several hundred kilometres(km) from the accident site (Syzjyko). These findings suggest that the control of contaminated foodstuffs and the institution of iodine prophylaxis were not effectively implemented. This paper concentrates on the public health hazards from the uptake of radioiodines and reviews the case to improve the distribution of stable iodine as an intervention in contingency plans.

**Background**

Nuclear plant emergency contingency plans are in place to protect public health utilising a number of interventions: sheltering, control of foodstuffs, evacuation, and also stable iodine prophylaxis. These would be employed on the basis of averting the dose to individuals, thereby reducing the risk of stochastic effects. The "averted dose" concept aims at ensuring that interventions result in a net benefit to public health. Most interventions entail some degree of hazard and also costs, both economic and social. No single intervention should be seen in isolation and their relative merits depend on the actual threat to public health, which may vary with according to the circumstances of the emergency. For distribution of stable iodine the relevant factors to be considered are the:

- extent to which thyroid disease can be averted by risks of side effects from stable iodine
- costs, social and economic, entailed in administration

Factors relevant to the first consideration are the:

- likelihood of further releases of $^{131}$I of public health significance size of population likely to be subject to a significant public
- health risk from such a release
- relationship between any exposure to the release and thyroid disease.

Factors relevant to the second and third consideration are the:

- hazards associated with the administration of stable iodine
- costs of providing, maintaining and distributing stocks of,
- stable iodine to the population potentially at risk

**Risk of future accidents**

Most commercial power generating reactors have been designed to high safety standards so that failures entailing reactor core damage and releases are rare (typically of the order of one in ten to one hundred thousand reactor years of operation). World wide, two major accidents have occurred to date, Three Mile Island and Chernobyl, during some 8000 reactor years of operation. In both accidents the reactor core was destroyed but in only one, Chernobyl, was there a significant release of radioiodine to the environment. Considering this past experience the maximum likelihood estimate of the probability of another serious accident in the decade following the Chernobyl accident was estimated to be not less than 0.25 (Edwards 1986) and for the current decade is estimated to be not less than 0.15 (Blomquist 1996). The disparity between the design risk of a technical failure leading to core damage and actual experience may be due to "human error", which was a feature in both accidents. Risks based on past experience do not necessarily apply to the future as important lessons have been learned.

**Thyroid doses after a release.**

Radioiodine in the atmosphere is carried by prevailing winds mainly as a gaseous cloud, and deposits by absorption on to foliage, including the grass. Precipitation will considerably enhance the deposition process. There are thus two main routes by which radioiodine may enter the body, inhalation from the cloud and through the food chain, principally from drinking milk from cows that have eaten contaminated pasture and, to a lesser extent, from the consumption of contaminated vegetables

Close in to the Chernobyl plant doses to the thyroid would have arisen from inhalation of radioiodine, with contributions from tellurium -132 ($^{132}$Te) (which decays rapidly to $^{132}$I). Further afield inhalation ceases to be important and ingestion of $^{131}$I, primarily from fresh milk, dominates dose. External irradiation from the cloud from other isotopes could also have contributed to the thyroid dose. Estimates suggest that the contribution of all the radioiodine and $^{132}$Te could have accounted for up to 50% of the dose by inhalation close to Chernobyl during the first day after the accident but only about 10% of the total dose if the intake occurred by both inhalation and the later ingestion of contaminated foodstuffs.(Khrouch et al (1988) Indeed dose reconstructions in Belarus (Gavrilin 1996), the Russian Federation (Zvonova 1993) and the Ukraine (Likhtarev 1993) all to populations at considerable distances from the source suggested that, in practice, the bulk of iodine uptake resulted from ingestion of contaminated milk and leafy vegetables. This is a general feature of iodine releases and has been seen at the Windscale pile accident(Baverstock and Vennaart) and following the Nevada US weapons testing programme.(NCI)

**Risks of thyroid cancer resulting from exposure to radioiodine**

X-ray exposures have been used to treat a number of childhood conditions, such as tinea capitis, enlarged thymus and tonsillitis, and follow-up of these populations has indicated the sensitivity of the child's thyroid to external radiation. A pooled analysis of these studies shows the combined absolute risk for all childhood exposure is 4.4 per 10000 person-year-Gray (PYGy). (Ron et al. 95) A strong age dependency of risk was noticed, small children being at higher risk. Conversely, external radiation has not been shown, with certainty, to cause thyroid cancer in adults. In the Japanese Life Span Study the risk for thyroid cancer in persons exposed between age 20 and 40 was not significant, and no risk was identified in those over 40 (Thompson et al. 94).

$^{131}$I has been extensively used in the treatment and diagnosis of thyroid disorders and again follow-up of exposed groups has been carried out. In contrast to the situation for x-ray exposures little or no induced disease has been reported (Ron 96). However, the majority of treated people have been adults. Prior to the Chernobyl accident, there were very little data upon which to determine the effect of $^{131}$I in children.

Thus, what has generally been believed to be an essential difference in carcinogenic potential between external radiation and $^{131}$I is, in reality, an age effect. The sensitivity in adults to both external radiation and $^{131}$I seems to be minimal or even absent in some age groups, while the sensitivity in small children is high. Indeed experience now accruing from the follow-up of the Chernobyl accident (Baverstock 93, Jacob et al. 98) suggests that there is little difference in the risks associated with exposure to x-rays and $^{131}$I. Thus, for public health purposes equivalence of carcinogenic effect between x-rays and $^{131}$I may be assumed.

**Lessons from the increase in childhood thyroid cancer after Chernobyl**

In the period 1990-95 has amounted to more than 600 childhood thyroid cancer cases have been reported.(Williams et al. 96). The increase in thyroid cancer has been observed up to 500 km from the accident site, well beyond typical emergency planning zones. This emphasises the importance of being able to protect children in locations remote from the sites of potential accidents. Also, while small children in the most severely contaminated areas close to the accident received mean thyroid doses several Gy, (and the cancer incidence in these areas have been correspondingly higher) the majority of the cases have occurred in children who received less than 300 mGy. This was true for almost 80% of the cases in Ukraine.(Tronko et al. 96). The public health significance of low doses is illustrated by the fact that in Belarus, among 300000 children under the age of six exposed to an average thyroid dose as low as 60 mGy, 84

cancer cases have been recorded (Buglova et al. 97). Only two cases would have been expected in the same time without radiation exposure.

A recent dose-response-analysis for all children based on data from the three affected countries reported that the combined risk for those born 1971-1986 was 2.3 per 10000 PYGy (Jacob et al. 98). Besides being subject to a greater risk per dose, small children can also receive thyroid doses several times higher than adults in case of a release of radioiodine due to the smaller size of their thyroid gland and their higher intake of radioiodine from contaminated milk in relation to their body mass. So in the countries affected by the Chernobyl accident the highest incidence of thyroid cancer has been observed in children less than six years old at the time of exposure. If the risk per year is assumed to persist unchanged for 40-50 years, this means a lifetime risk for those exposed as children of the order of 1-2 % per Gy.

On the other hand, from earlier experience cited above the risk for thyroid cancer in those exposed as adults is low, and it may well be almost zero in persons over 40 years of age. Although data from Belarus has been presented, indicating an increase in thyroid cancer in adults (Demidchik et al. 96), the increase started well before the accident, and it is evident that any possible real increase in young adults is likely to be masked by a more efficient registration of cases. In later years, increased ascertainment from an improved thyroid screening effect leading to detection of clinically indolent, or occult, tumours may also have contributed to the apparent increase.

**Administration of stable iodine**

There is only one published record of widespread administration of stable iodine and this was in Poland, where stable iodine was distributed as a single dose to 10½ million children; no serious side effects were seen (Nauman and Wolff 93). In 7 million adults, taking iodine against recommendation, two cases of serious allergic reaction were observed. On this basis, the frequency of serious side effects was less than $10^{-7}$ in children and less than $10^{-6}$ in adults. Minor side effects, such as, mild skin rash or gastrointestinal complaints, were not uncommon. In some new-born children, who were given 30 mg potassium iodide in the first few days of life, a reversible rise in thyroid stimulating hormone (TSH) was seen. This has been confirmed in chimpanzee experiments which show that daily doses of stable iodine over a ten day period leads to a reversible rise in TSH but had no effect on thyroid function. (Noteboom.1(1997)). Similar results were also found in pregnant chimpanzees in protection of the fetal thyroid. (Noteboom.2 1997). These experiments also confirm the effectiveness of stable iodine as a blocking agent.

**The costs of stable iodine administration**

The principal costs of stable iodine administration are in the planning, production, storage and maintenance of stocks and the arrangements for distribution(Becker (1997). Since, to be effective stable iodine must be distributed before or as soon after exposure as possible some form of pre-distribution or stock piling is required together with a method of rapid distribution and the provision of public information in the event of an emergency.

**Finding the balance between risk and benefit**

Using a lifetime cancer risk for childhood thyroid cancer of 1% per Gy and the risk of serious side effects from a single dose of stable iodine of $10^{-7}$, a risk-benefit analysis gives a balance between the risk and the benefit, based on health consequences, of 0.01 mGy thyroid dose. This would suggest that the risk of side effects can be ignored when deciding on an intervention level for stable iodine prophylaxis as a single dose to children. So decisions would not be based on health considerations but social and economic costs. An important and very relevant issue for contingency planning, however, is to further balance the undoubted benefits from iodine administration and the effectiveness of other interventions, such as shelter and control of contaminated foodstuffs.

For children a mean thyroid dose of 10 mGy would give rise to a ten fold increase in thyroid cancer over ten years; this increase would be measurable against the natural incidence of childhood thyroid cancer which is around 0.3 per million per year. Protecting children from thyroid cancer is important. It is not usually fatal but requires long term therapy leading to impairment of their quality of life and the costs of treatment may be considerable. Even if "avertable dose" was grossly overestimated no net harm to health would result from stable iodine administration.

For adults, because of the low cancer risk and the low risk of side effects the balance is probably in favour of iodine administration, however, in people over 40, the cancer risk is probably close to zero. In that case, the administration of stable iodine has no benefit, unless predicted doses approach levels which pose a threat to thyroid function, that is several grays.

If it is not possible to control foodstuffs stable iodine may need to be given daily for several weeks. The frequency of side effects from repeated doses in humans is not known. For pregnant women it may be prudent to avoid repeated doses. Generally,

agricultural measures to prevent uptake of $^{131}I$ in milk and food, with milk controls and provision of milk powder, are the preferred interventions.

**Summary**

Interventions to protect public health from exposure to radioactive iodine should not be seen in isolation. The benefits for children of the administration of stable iodine seen against the low risk of side effects, and the need for rapid implementation argue in favour of robust plans so that, if indicated, early distribution can be effectively carried out. Prevention of exposure through control of foodstuffs is the preferred intervention but if this is not possible then iodine prophylaxis is essential. There is a need for greater public awareness of the implication of such releases and their mitigation by stable iodine. When informing the public, it should be stressed that small children are at greatest risk from radioiodine uptake, while the risk for young adults is low and for the elderly probably very low.

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Article: 1095 of sgi.talk.ratical
From: davc@sgi.com (dave "who can do? ratmandu!" ratcliffe)
Subject: *Nature* 9/92: **Thyroid Cancer 7.5 years after Chernobyl, soaring**
Summary: **fallout from Chernobyl "on schedule" despite Official "No Danger" Myths**
Keywords: **thyroid carcinoma, fetal thyroid concentrating iodine**
Date: 25 Jun 1995 21:15:11 GMT
Organization: Silicon Graphics, Inc.
Lines: 341

One of the most pervasive myths about Chernobyl is that only 3% of the reactor core was released into the biosphere when the explosion occurred on April 26, 1986. Vladimir Chernousenko, Scientific Director of the Ukrainian Academy of Sciences' Task Force for the Rectification of the Consequences of the Accident, in his 1991 book *Chernobyl, Insight from the Inside,* dispels this myth (and a partial list of 20 others), citing,

> A more official view on `The Nuclear Accident in Block 4 of the Chernobyl Nuclear Power Station and the Safety of the RBMK Reactor' give[s] the following excerpts from an unpublished report by A.A. Yadrikhinskii, Nuclear Safety Inspection Engineer of the USSR State Atomic Energy Survey Commission (Kurchatov town, RSFSR February, 1988):
>
> > . . . Radiation emission was no less that 80% of the core (with a total of 192 tons), which amounted to 6.4 x 10^9 Ci.[16] If we divide the figure by the population of the whole earth (4.6 x 10^9 people) then we get 1 Ci per person.[17]

Choosing to ignore the facts about how we are collectively contaminating this Earth with lethal-to-all-life-doses of man-made nuclear fission products will ensure the cessation of billions of years of life exploring itself on this planet. It doesn't have to go down this way. If we were living in the areas that the children described below are, we would not be able to ignore the facts which the International Nuclear Mafia continuously deny when they parrot the line in the global media about how "There's no health danger from nuclear power" and "No one died at Chernobyl" and "This form of energy is clean and safe; anyone who says otherwise doesn't know what they're talking about".

-- ratitor

from the *San Francisco Chronicle,* Thursday, September 3, 1992:
And see the June 30, 1999 Reuters story below regarding
**Thyroid cancer 10 times higher in Chernobyl kids**

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**Thyroid Cancer on Rise For Chernobyl Children**

New York

Children who were exposed to radiation from the Chernobyl nuclear power plant disaster are developing thyroid cancer sooner and in larger numbers than expected, researchers report.

The results are the first reliable data in the population downwind of the Chernobyl accident in 1986, said Dr. Marvin Goldman, a radiation biologist at the University of California at Irvine who was not involved in the new study.

An increase in thyroid cancer had been reported earlier, but some Western health officials had expressed concern about the reliability of the data.

In a letter published yesterday in *Nature*, a British science journal, Dr. Vasily S. Kazakov of the Belarus Ministry of Health in Minsk and his colleagues say that the thyroid cancer rates in the regions most heavily irradiated began to soar in 1990.

In Gomel, the most contaminated region studied, there used to be just one or two cases of thyroid children a year. But Kazakov and his colleagues found that there were 38 cases in 1991. In six regions of Belarus and the city of Minsk, the investigators found 131 cases of thyroid cancer in young children, some of whom were still in the womb when the Chernobyl accident occurred.

Because of questions about the cancer reports, the World Health Organization sent a team of scientists to Minsk to verify the reports. In an accompanying letter in *Nature* yesterday, they confirmed Kazakov's results.

Children are particularly susceptible to thyroid cancer from radioactive iodine because their thyroid glands are small and concentrate the iodine from radioactive fallout because they drink more milk and get larger doses of radioactive iodine and because their thyroids are thought to be more vulnerable to the radiation.

Thyroid cancer is usually very amenable to treatment, said Dr. Blake Cady, a cancer surgeon and thyroid cancer specialist at the New England Deaconess Hospital in Boston. But investigators were struck by the seeming aggressiveness of some of the children's cancers. A 7-year-old child died and 10 other children are seriously ill, they reported.

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*NATURE,* Vol. 359, 3 SEPTEMBER 1992

SCIENTIFIC

CORRESPONDENCE

Thyroid cancer after Chernobyl

SIR--We would like to report a great increase in the frequency of thyroid cancer in children in Belarus, which commenced in 1990 and continues. Table 1 shows the

incidence of thyroid cancer in children in the six regions of Belarus and Minsk City from 1986 to the end of the first half of 1992. It can be seen that the overall incidence rose from an average of just four cases per year from 1986 to 1989 inclusive, to 55 in 1991 and is projected to be not less than 60 in 1992. This increase is not uniformly distributed across the country: for example, there is no significant increase in Mogilev, Minsk City or Vitebsk. By far the greatest increase is seen in the Gomel region, from one or two cases per year to 38 in 1991, and a less obvious increase is seen in the Brest and Grodno regions.

TABLE 1 Incidence of thyroid cancer in children in Belarus

| Region of Belarus | Years 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992* | Total |
|---|---|---|---|---|---|---|---|---|
| Brest | 0 | 0 | 1 | 1 | 6 | 5 | 5 | 18 |
| Vitebsk | 0 | 0 | 0 | 0 | 1 | 3 | 0 | 4 |
| Gomel | 1 | 2 | 1 | 2 | 14 | 38 | 13 | 71 |
| Grodno | 1 | 1 | 1 | 2 | 0 | 2 | 6 | 13 |
| Minsk | 0 | 1 | 1 | 1 | 1 | 4 | 4 | 12 |
| Mogilev | 0 | 0 | 0 | 0 | 2 | 1 | 1 | 4 |
| Minsk City | 0 | 0 | 1 | 0 | 5 | 2 | 1 | 9 |
| Total | 2 | 4 | 5 | 6 | 29 | 55 | 30 | 131 |

* Six months of 1992

The Gomel region lies immediately to the north of Chernobyl and is known to have received a high level of radioactivity as fallout after the breakdown of reactor number 4 on 26 April 1986. The plume passed first over the Gomel region in the first few hours after the major release of radioactivity, and then over the Brest and Grodno regions. The fallout contained large amounts of iodine-131 and significant amounts of the short-lived isotopes of iodine, although these were too short-lived to be measured.

We have classified the tumours according to the World Health Organisation classification (2nd edn) and find that virtually all are papillary carcinomas (128 of 131). They are, however, relatively aggressive, as can be seen from Table 2. Fifty-five of the 131 cases showed direct extension to the perithyroid tissues and six distant metastases, mostly in the lungs. It can be seen that only about 23 per cent were less than 1 cm in diameter. One of the children has died at seven years of age and ten others are seriously ill.

TABLE 2 Extent of spread (TNM classification) of thyroid cancer in children

| | TNM symbol | Total number of cases | Lymph node metastases: None (N 0) | Ipsilateral (N 1a) | Other (N 1b) |
|---|---|---|---|---|---|
| Tumour size | | | | | |
| <1 cm | T1 | 30 | 17 | 10 | 3 |
| 1-4 cm | T2 | 33 | 17 | 8 | 8 |
| >4 cm | T3 | 7 | 3 | 4 | 0 |
| Extending to surrounding | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| tissues | T4 | 55 | 14 | 18 | 23 |
| | | Distant | | | |
| metastases | M1 | 6 | 1 | 1 | 4 |
| Total | | 131 | 52 | 41 | 38 |

Classification as in *TNM Atlas* 3rd edn, eds Spiessl, B. *et al.*, UICC (Springer, Berlin, 1990).

The occurrence of this increase in thyroid cancer in children within a few years of exposure to radioactive isotopes of iodine is unexpected, but real. It poses both humanitarian and scientific problems, and is placing great strains upon the health services of our new country. It also provides an opportunity, which we hope will not be repeated, to study the consequences of major exposure of a population to isotopes of iodine from fallout. We are collaborating with several international groups and are preparing detailed reports of various aspects of the problem.

We believe that the only realistic explanation for the increase in the frequency of thyroid cancer is that it is a direct consequence of the accident at Chernobyl.

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SIR--We have recently visited Belarus under the auspices of the WHO regional office for Europe and the Swiss government, and have had the opportunity to see some of the children with thyroid cancer, to study the pathology of the cases and to examine the relevant data.

We examined 11 children who had had operations for thyroid carcinoma and were now hospitalized for post-operative management or evaluation of metastatic disease. We were shown the complete records for these patients, including X-rays and echograms before and after treatment. All were diagnosed during the past 3 years, eight having been living in the Gomel region at the time of the Chernobyl accident and two in the Brest region. The age at diagnosis of the six females and five males was between 4 and 13 years of age; the youngest was born two days after the accident.

We have studied the histological slides from 104 cases of children from Belarus in whom the diagnosis of thyroid carcinoma had been made since January 1989. We agree both with the diagnosis of malignancy and of the type of malignancy in 102 of the cases. We also examined the data on the incidence of thyroid carcinoma in Belarus. There is a marked increase in frequency from 1990 onwards over the average for the years from 1986 to 1990. This increase started only 4 years after the Chernobyl accident, a surprisingly short time by comparison with studies of thyroid carcinoma that have followed exposure to external radiation in infants [1,2]. Of the children with thyroid carcinoma in Belarus since 1990, the eight youngest at exposure were *in utero*, but were more than 3 months of fetal age at the time of Chernobyl. The fetal thyroid is known to start concentrating iodine at 12-14 weeks of gestation.

We do not believe that increased ascertainment of cases could have played more than a minor role in the recorded incidence of thyroid carcinoma. The proportion of resected nodules that are malignant is high and the type of tumour is aggressive. The ratio of thyroid carcinoma in children to that in adults has increased dramatically, although there are now signs that the incidence in patients over the age of 15 is beginning to increase. The rate is greatly in excess of the reported incidence of this disease in children under 15 years of age, which is of the order of I per million per year[3-6]. In the Gomel region (total population about 2.5 million), the region of Belarus that received the highest fallout from Chernobyl, the incidence in 1991 and the first part of 1992 is approximately 80 per million children per year.

It is generally accepted that external radiation to the neck is associated with an increased incidence of thyroid carcinoma in man, and there is an increased sensitivity of the infant thyroid to the carcinogenic effect of radiation [2]. In some animal studies, but not all [7,8], external radiation is found to be a more effective carcinogen for the thyroid than iodine-131. Clear evidence that the diagnostic or therapeutic use of radioiodine in man carries a carcinogenic risk is lacking [9,10], and iodine-131 has provided a safe and effective treatment of Graves' disease in adults, although it is rarely used in young children.

The combination of the high level of exposure to radioactive fallout and the numbers exposed within a short time after its release makes the Chernobyl accident an unprecedented event. In the Marshall Islands, although the doses were probably comparable, the number of people exposed was several orders of magnitude smaller [11]. In the case of the accident at Windscale (now called Sellafield), the number exposed was substantial but the doses were smaller [12], and no adequate study of any long-term thyroid effects has yet been reported. Other studies of fallout from weapons and of nuclear accidents (such as on Three Mile Island) have yielded inconclusive evidence. A close relationship between radiation dose and the incidence of thyroid carcinoma has been documented in atomic bomb survivors in Japan [13], but the radiation received was mostly external and the contribution from fallout is uncertain.

We believe that the experience in Belarus suggests that the consequences to the human thyroid, especially in fetuses and young children, of the carcinogenic effects of radioactive fallout is much greater than previously thought. Studies of the Marshall Islanders, of the atomic bomb survivors and of the effects of external radiation on the

thyroid suggest that the incidence of thyroid cancer in Belarus will be raised for many years.

The accident and its impact on Belarus poses a challenge to the international community to help, both in dealing with the extensive present and future public health consequences, and in promoting research for the understanding of the basic processes underlying the phenomenon. Understanding the consequences of Chernobyl will provide an important basis for preventive action in future.

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. . . the number of children and grandchildren with cancer in their bones, with leukemia in their blood, or with poison in their lungs might seem statistically small to some, in comparison with natural health hazards, but this is not a natural health hazard--and it is not a statistical issue. The loss of even one human life, or the malformation of even one baby--who may be born long after we are gone--should be of concern to us all. Our children and grandchildren are not merely statistics toward which we can be indifferent.

-- President Kennedy, June, 1963

**Thyroid cancer 10 times higher in Chernobyl kids**
Wednesday, June 30, 1999

WASHINGTON (Reuters) - The rate of thyroid cancer remains 10 times higher than normal among young Ukrainian children 13 years after the accident at the Chernobyl nuclear power plant, researchers said Wednesday.

They reported 577 cases of thyroid cancer in Ukrainian children between 1986, when the accident occurred, and 1997, compared to 59 cases in the same age group from 1981 to 1985.

The reactor at Chernobyl caught fire in the early hours of April 26, 1986, spreading a radioactive cloud over much of Ukraine, Russia, Belarus and other parts of Europe. It killed 31 people and affected thousands more.

In Belarus, where 70 percent of the radiation was deposited, the World Health Organization says thyroid cancer rates among children are 100 times pre-accident levels.

"Children constitute the most vulnerable group of exposed individuals, because their thyroid sensitivity to radiation is high, and there is a longer life span to manifest its effects," Dr. Virginia LiVolsi of the University of Pennsylvania Medical Center in Philadelphia, said in a statement.

"These factors make it necessary to follow thyroid function in exposed subjects for decades."

Reporting in the journal cancer, LiVolsi said her team found that 64 percent of all Ukrainian thyroid cancer patients aged 15 or younger lived in the most contaminated regions -- the provinces of Kiev, Chernigov, Zhitomir, Cherkassy and Rovno.

More than 40 percent of patients were children 4 or younger at the time of the accident.

"The group at maximum risk is those exposed to high radiation levels when they were younger than 5 years," LiVolsi said. "This is the age when the thyroid gland is most sensitive to ionizing radiation."

The American Cancer Society predicts that more than 18,000 adults in the United States will be diagnosed with thyroid cancer in 1999. About 1,200 will die.

There is a way to help prevent thyroid cancer caused because of exposure to radioactivity. In Poland, where potassium iodide was given to 97 percent of children, there has been no similar increase in thyroid cancer although the country was also exposed to radioactive clouds from Chernobyl.

Last week the U.S. Nuclear Regulatory Commission proposed that potassium iodide be stockpiled to protect the public from a major release of radiation during a nuclear power plant accident.

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**Subject:** BBC News | Health | 'Chernobyl cancer might have been prevented'
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**To:** Pixie Lampert <jlampert@idt.net>, Stewart Farber <radproject@aol.com>, Bob Hallisey <bob.hallisey@state.ma.us>

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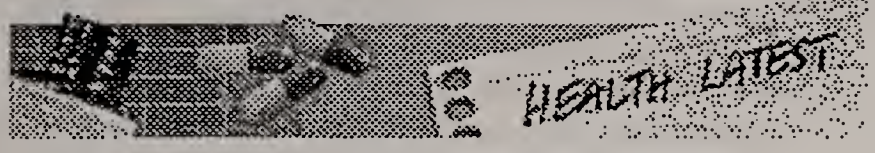
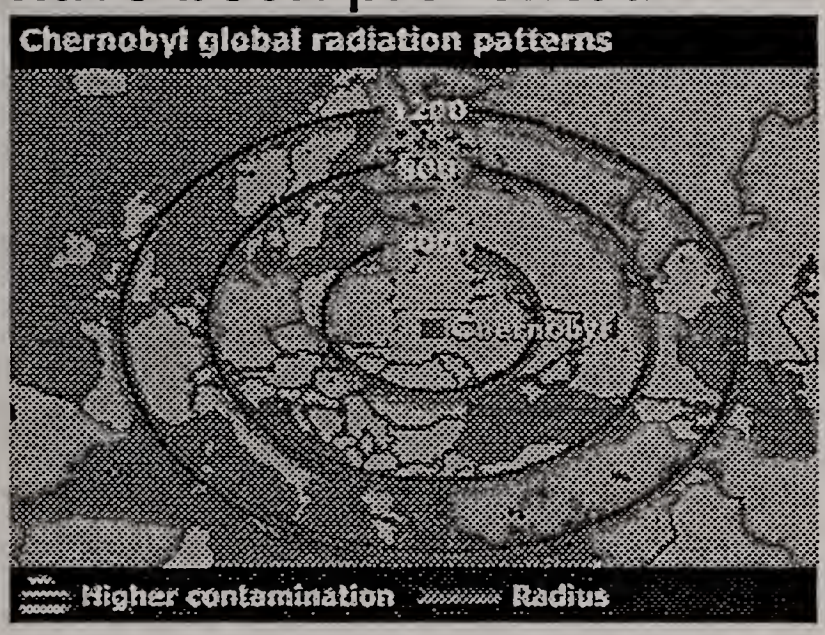



Thursday, July 1, 1999 Published at 15:43 GMT 16:43 UK

# Health

# 'Chernobyl cancer might have been prevented'




Fallout from Chernobyl covered much of Eastern Europe

The toll of thyroid cancer carried by the fallout from the Chernobyl nuclear disaster could have been prevented, new evidence suggests.

And a British cancer expert agrees that had a simple drug been given to young children in the former Soviet Union who were in the path of the radioactive cloud which covered much of Eastern Europe, much suffering could have been prevented.

The disaster, in 1986, happened when a reactor at Chernobyl, in the now-independent state of Ukraine, melted down, throwing large quantities of radioactive isotopes into the atmosphere.

One of these, radioactive iodine, is absorbed by the thyroid gland, particularly in very young children,

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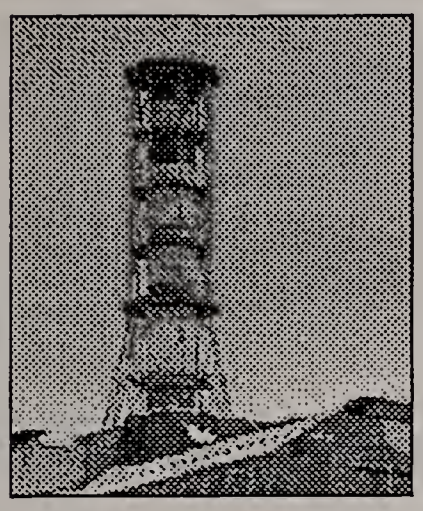
thyroid gland, particularly in very young children, where it can cause cancer, in some cases many years later.



The levels of contamination were highest in Belarus where, in one region, the rate of thyroid cancer in the very young was 100 times normal levels.

Lower pollution levels were comparable between Ukraine and Poland.

However, while a new study reveals the high incidence of thyroid cancer in young Ukrainian children - 10 times greater than normal levels, the levels in Poland have not yet risen significantly.

**Tablet handout was 'crucial'**

Many scientists believe that the swift distribution of potassium iodide tablets - which block the uptake of radioactive iodine into the thyroid - was crucial in preventing cancers.

Professor Sir Dilwyn Williams, who runs a thyroid cancer research unit attached to Cambridge University, says that a similarly prompt response by the then Soviet authorities could have made a huge difference.

He said: "One of the major lessons we have learned is the extreme sensitivity of the youngest children.

"They should have done more to make sure potassium iodide was available. That isn't impossible to do."

He said that he was sure that the mammoth efforts by the Poles, led by just one expert, to distribute the drug had prevented suffering.

**Public health doctors take charge**

In Britain, public health doctors in every health authority have been given detailed guidance on how and when to distribute potassium iodide in the event of a radioactive disaster.

The guidance stresses that the drug must if possible be given within three hours of any exposure to radioactive iodine.

It suggests that some pills should be distributed in advance to inaccessible households, police stations, hospitals and pharmacies.

Britain is ahead of the US in this respect - proposals to

Relenza: the reaction

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Mental health blueprint: The reaction

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Experts back 'superhospitals'

stockpile potassium iodide at nuclear power stations were only put forward last week after years of lobbying.

Thyroid cancer, which often does not manifest itself for several years after exposure, is usually a very treatable cancer, either by surgery, chemotherapy, hormone treatment, or ironically, radiotherapy.

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# Juvenile Hypothyroidism among Two Populations Exposed to Radioiodine

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We found an epidemic of juvenile hypothyroidism among a population of self-defined "downwinders" living near the Hanford nuclear facility located in southeast Washington State. The episode followed massive releases of $^{131}I$. Self-reported data on 60 cases of juvenile hypothyroidism (<20 years of age) among a group of 801 Hanford downwinders are presented, as well as data concerning the thyroid status of approximately 160,000 children exposed to radioiodine before 10 years of age as a result of the 26 April 1986 Chernobyl explosion in the former Soviet Union. These children were residents of five regions near Chernobyl. They were examined by standardized screening protocols over a period of 5 years from 1991 to 1996. They are a well-defined group of 10 samples. Fifty-six cases of hypothyroidism were found among boys and 92 among girls. Body burdens of $^{137}Cs$ have been correlated with hypothyroidism prevalence rates. On the other hand, the group of juvenile (<20 years of age) Hanford downwinders is not a representative sample. Most of the 77 cases of juvenile hypothyroidism in the Hanford group were diagnosed from 1945 to 1970. However, the ratio of reported cases to the county population under 20 years of age is roughly correlated with officially estimated mean levels of cumulative thyroid $^{131}I$ uptake in these counties, providing evidence that juvenile hypothyroidism was associated with radioiodine exposures. Because even subtle hypothyroidism may be of clinical significance in childhood and can be treated, it may be useful to screen for the condition in populations exposed to radioiodine fallout. Although radiation exposure is associated with hypothyroidism, its excess among fallout-exposed children has not been previously quantified. *Key words:* Chernobyl, downwinders, exposed children, $^{131}I$ contamination, $^{131}I/^{137}Cs$ body burden, Hanford, hypothyroidism, radiation, radioactive fallout, TSH, thyroid, thyroid-stimulating hormone. *Environ Health Perspect* 107:303–308 (1999). [Online 15 March 1999]
*http://ehpnet1.niehs.nih.gov/docs/1999/107p303-308goldsmith/abstract.html*

Hypothyroidism is a potential environmental hazard associated with ingestion, physiological uptake, and concentration of radioiodine by the thyroid. Congenital hypothyroidism is well known. Acquired hypothyroidism in childhood (<20 years of age) is uncommon, though dependent on natural environmental iodine levels. Its onset is insidious and the importance of prompt recognition of the condition is related to its association with impairment of physical and mental development, as documented by the initial findings in an exposed Marshall Island population (*1*). Because hypothyroidism can easily and successfully be treated, its detection is clinically important. Therapeutic high-dose radiation exposure to the head and neck is a known risk factor and the association of delayed hypothyroidism following treatment of hyperthyroidism with $^{131}I$ has long been recognized (*2*).

We present data about hypothyroidism in children exposed to fallout from Chernobyl in the former Soviet Union, as well as data about hypothyroidism in juveniles exposed to radioactive emissions from the Hanford, Washington, plutonium manufacturing plant.

## Materials and Methods

*Hanford area.* The Hanford nuclear site in eastern Washington State was established in 1943 as part of the Manhattan Project. It produced $^{239}Pu$ for use in nuclear bombs. The original reactors became operational in 1944. In 1986 it was officially revealed that there had been releases of large quantities of gaseous and particulate radionuclides, especially between 1944 and 1952, of which $^{131}I$ (half-life 8 days) was a major component. Shorter- and longer-lived isotopes of radioiodine such as $^{132}I$ (2.3 hr), $^{133}I$ (21 hr), $^{135}I$ (0.28 days), and $^{129}I$ (17 million years) were also released.

Although there is considerable uncertainty about the amount of radioactivity released, an estimate of 550,000 Ci in 1945 and 166,000 Ci of $^{131}I$ during 1946 through 1952 has been reported (*3*). The Hanford Environmental Dose Reconstruction (HEDR) project found strong evidence that thyroid glands of large numbers of individuals, particularly children, were likely to have been exposed to doses in the range of several hundred rad depending on where they lived and what they ate and drank (*3*).

Many residents of the counties potentially affected (mainly in eastern Washington, northeastern Oregon, and Idaho—west of the Rocky Mountains) (Fig. 1), who call themselves "Hanford downwinders." These citizens reported a lack of interest in their chronic and serious health complaints and denial of possible associations with radioactive fallout by both their physicians and federal and state public health agencies. The Hanford downwinders also experienced rejection of possible accountability by appropriate state or federal public health agencies.

A group of downwinders sought and obtained support from volunteer scientists and physicians of the Oregon Chapter of Physicians for Social Responsibility. They, together with local downwinders and environmental activists, undertook this survey of serious health problems. These downwinders and volunteers joined to form the Northwest Radiation Health Alliance, which developed a questionnaire covering personal information, information related to likely exposure, and a wide spectrum of health problems. Between 1,500 and 2,000 questionnaires were distributed through an informal network of concerned downwinders (who did not keep records of exact numbers), followed by a return of 801 usable reports. The diagnosis of hypothyroidism (including year of diagnosis) was assigned to all persons who responded that their physicians had diagnosed them as having hypothyroidism and who had been taking thyroid supplements. A follow-up random sampling of informants by telephone established that most of the diagnoses had been based on blood tests and a few had been based on breathing tests for basal metabolic rate. Postthyroidectomy

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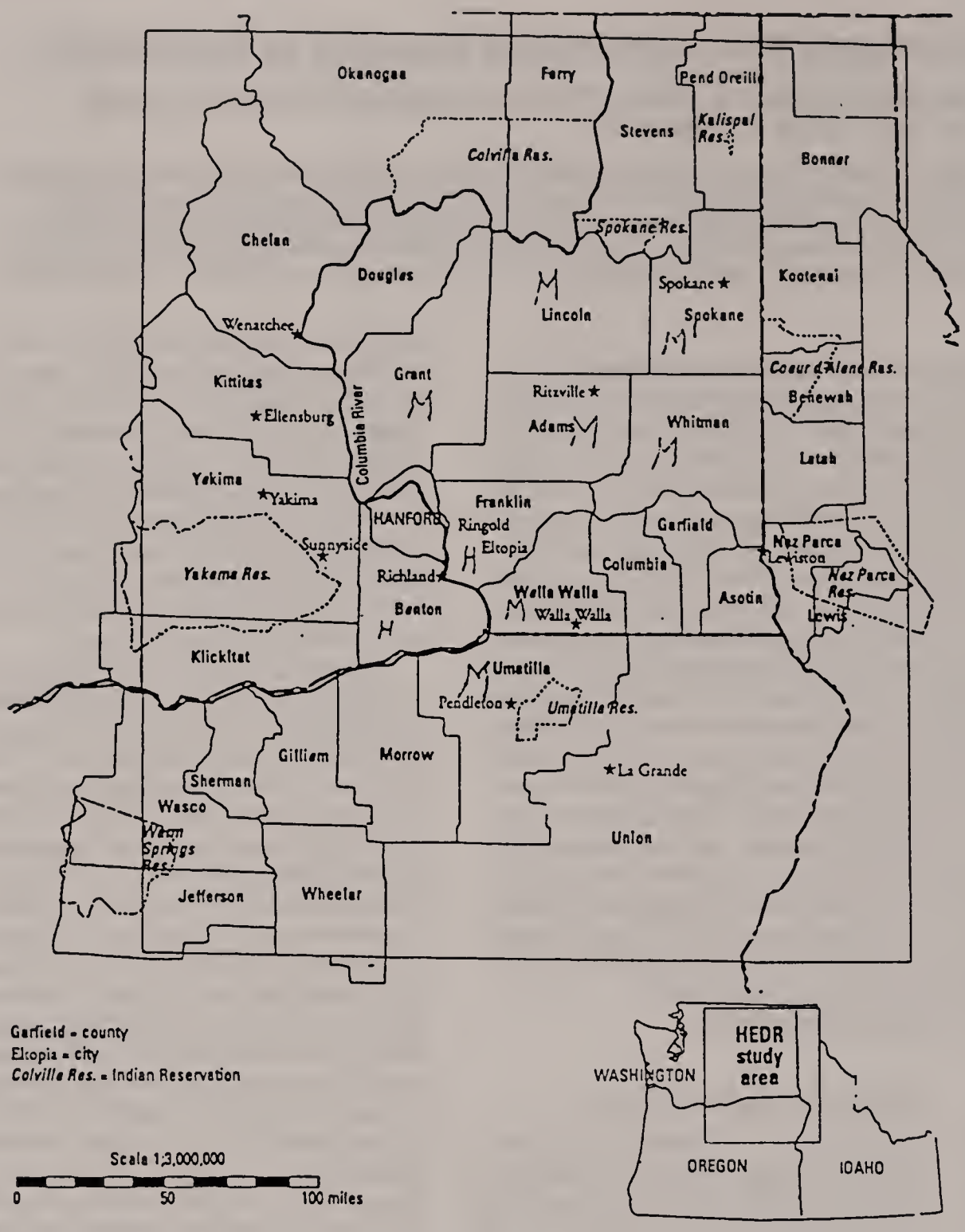


Figure 1. Counties around the Hanford, Washington, plutonium manufacturing plant included in the Hanford Environmental Dose Reconstruction Project (3).

hypothyroid cases taking thyroid were excluded from our counts.

*Chernobyl area.* Massive emissions of radioiodine (including $^{129}I$, $^{131}I$, $^{132}I$, $^{133}I$, and $^{135}I$, with half lives of $1.72 \times 10^7$ years, 8.0 days, 0.096 days, 0.875 days, and 28 days, respectively) occurred on 26 April 1986, as a result of the explosion of one of the Chernobyl reactors. Emissions of many other isotopes, such as $^{137}Cs$, also occurred, but because of the short half-lives of all but one of the radioiodines, it is difficult to estimate the distribution of thyroid doses several years later. Conversely, $^{137}Cs$ has a 30.2-year half-life and shows gradients both for ground-level contamination and for estimated body burdens for individuals and might, thus, serve as proxy for early radioiodine uptake. With support from the Nippon Foundation (Tokyo) through the Sasakawa Memorial Foundation (Tokyo), five regional screening centers were established in regions adjacent to the Chernobyl plant, and each was provided with the same equipment, protocol, and staff training for a screening study of children who were up to 9 years of age at the time of the disaster. Thyroid volume was determined by ultrasonography and provided the basis for statistical evaluation of goiter. Goiter prevalence varied from 18% in the Gomel region to 54% in the Kiev region. Whole body $^{137}Cs$ burden was determined and served as an exposure index, although it was recognized that radiocesium, which follows a different precipitation pattern, was a poor index of exposure to gaseous radioiodine. The ratio of $^{131}I/^{137}Cs$ varies nonlinearly with $^{137}Cs$ concentrations. The ratio also varies significantly between geographic regions (4). In addition, migration of the population could have distorted the possible association of radiocesium with hypothyroidism.

The plans for the Chernobyl-area study were initiated in 1990 by the Nippon Foundation at the request of the administration of the USSR. The Japanese planning committee developed a protocol for the study and selected the equipment for use in screening. The screening equipment was installed in 1991. The Chernobyl Sasakawa Health and Medical Cooperation Project was completed and a final conference was held 14–15 October 1996 in Kiev, Ukraine. The presentations and data produced were published (5). The data include the following: 1) the number of children studied, by sex and age at the time of the explosion; 2) the year of examination, 3) the place of residence, and usually the district of residence (at the time of the explosion), 4) the results of thyroid examinations by ultrasound and by thyroid function tests, 5) the hematological indices, 6) the results of $^{137}Cs$ body burden estimations, and 7) the year of examination. The study used both standardized equipment and protocols, thus assuring uniformity in the data and a high level of quality. Hypothyroidism was defined as free thyroxin ($T_4$) <10 pmol/l and thyroid-stimulating hormone (TSH) >2.9 μIU/ml as tested by an Amerlite hormone analyzer (Amersham, Tokyo) using an immunometric technique based on enhanced luminescence. We included in our review only those communities with two or more cases of hypothyroidism of either sex.

Table 1 shows the number of individuals who were tested for TSH and $T_4$ according to sex, age, and residence at the time of the Chernobyl accident.

## Results

We present ratios of reported hypothyroid cases per number of respondents alive during 5-year periods, normalized per year and per 100,000 (Table 2, Fig. 2) for Hanford downwinders, whereas rates per 10,000 children at risk are given for the Chernobyl population.

*Hanford downwinders.* Table 2 shows the number of reported juvenile hypothyroid cases and all juvenile respondents alive, in 5-year time periods during which the condition was diagnosed, as well as ratios per 100,000 per year in our group. For comparison the same information is provided for adults in our study group. Of the 60 cases of juvenile hypothyroidism in our group, 54 were females and 6 males. Figure 2 presents the ratios from Table 2.

The onset of hypothyroidism was strongly associated with the years of reported maximum radioiodine releases, 1944–1949; onset reached a maximum approximately 15 years later in juveniles, then dropped off. The ratios for juveniles after 1960 become rapidly insignificant, perhaps due to the decline in the number of juvenile respondents in our group (Table 2). Most of the juvenile hypothyroid cases were exposed as children <10 years of age. The ratios for adult hypothyroidism appeared to rise more rapidly (Fig. 2), reaching a maximum only 5 years after the heaviest radioiodine releases, and they remained high until the end of our survey in 1997, as compared to pre-1944 values. A separate report about adult hypothyroidism in this group is in preparation.

Table 3 shows the distribution of cases of juvenile hypothyroidism by county (those included in the HEDR study) (*3*), the population <20 years of age, and the ratio per 100,000 population <20 years of age for the 1950 census (*6*). These ratios by county are shown in Figure 3 against the background of isopleths of estimated cumulative $^{131}I$ thyroid dose (in rad) to a child from exposure to all pathways for the years 1944 through 1951 (assuming milk came from cows on fresh pastures) (*3*). Keeping in mind that much of the county data are based on small numbers of cases (Table 3), and the large uncertainties in the estimated HEDR doses, there is reasonable concordance between estimated thyroid doses and the case rates.

The downwinders' questionnaire included a question for parents as to whether their child (or children) had reported learning disabilities. Of 136 traceable children without hypothyroidism, 37 had learning disabilities. Of 10 traceable children with hypothyroidism, 4 children had learning disabilities, in contrast to the 2.7 expected.

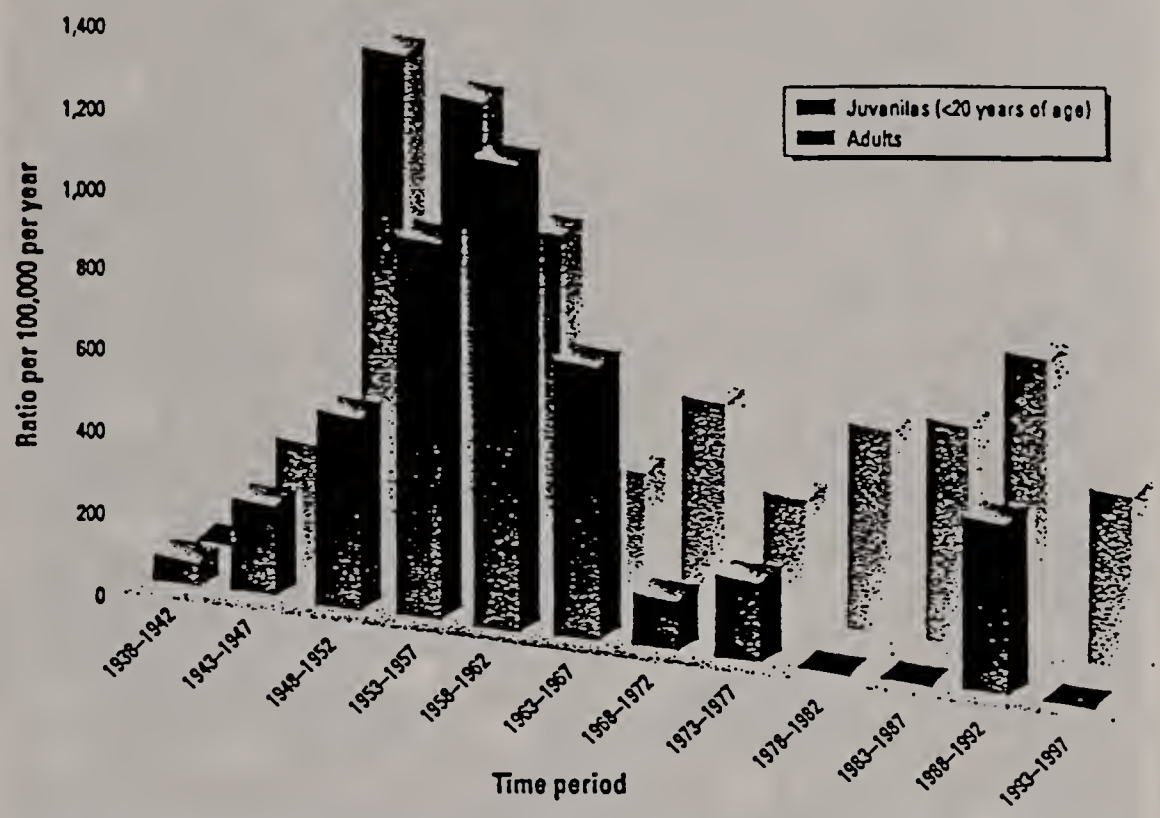


**Figure 2.** Self-reported hypothyroidism in a group of juvenile (<20 years of age) and adult Hanford downwinders by 5-year periods of diagnosis. Converted to ratio per 100,000/year.

**Table 1.** Populations[a] by age, sex, and location (region), studied by the Chernobyl–Sasakava health and medical cooperation project, who had thyroxin and thyroid-stimulating hormone tests (*5*)

| | Gomel | | Zhitomir | | Mogilev | | Bryansk | | Kiev | |
|---|---|---|---|---|---|---|---|---|---|---|
| Age[b] | Boys | Girls | Boys | Girls | Boys | Girls | Boys | Girls | Boys | Girls |
| <1 | 1,390 | 1,400 | 1,657 | 1,691 | 1,581 | 1,492 | 1,092 | 1,107 | 1,682 | 1,651 |
| 1 | 1,372 | 1,369 | 1,656 | 1,708 | 1,460 | 1,424 | 1,165 | 1,076 | 1,737 | 1,824 |
| 2 | 1,285 | 1,324 | 1,693 | 1,785 | 1,436 | 1,423 | 1,254 | 1,114 | 1,890 | 1,839 |
| 3 | 1,246 | 1,269 | 1,748 | 1,904 | 1,474 | 1,499 | 1,168 | 1,172 | 1,745 | 1,792 |
| 4 | 1,139 | 1,273 | 1,606 | 1,835 | 1,394 | 1,503 | 1,188 | 1,153 | 1,609 | 1,700 |
| 5 | 948 | 1,079 | 1,659 | 1,800 | 1,348 | 1,463 | 1,086 | 1,061 | 1,505 | 1,715 |
| 6 | 728 | 840 | 1,473 | 1,607 | 1,194 | 1,164 | 1,100 | 1,061 | 1,271 | 1,522 |
| 7 | 437 | 472 | 1,159 | 1,441 | 813 | 878 | 783 | 905 | 977 | 1,192 |
| 8 | 229 | 295 | 710 | 1,031 | 518 | 627 | 578 | 737 | 490 | 697 |
| 9 | 149 | 182 | 271 | 439 | 268 | 360 | 278 | 463 | 203 | 318 |
| Total | 8,923 | 9,503 | 13,632 | 15,241 | 11,486 | 11,833 | 9,692 | 9,849 | 13,109 | 14,250 |

[a]Total number of children seen, 1991–1996.
[b]At the time of the Chernobyl accident.

**Table 2.** Diagnoses of hypothyroidism in a group of self-selected Hanford, Washington, downwinders in 5-year periods

| | Juveniles (<20 years of age) | | | Adults | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| Period of diagnosis | Reported hypothyroid cases | Subjects alive during period[a] | Ratio per 100,000/year | Reported hypothyroid cases | Subjects alive during period[a] | Ratio per 100,000/year | Reported hypothyroid cases | Subjects alive during period[a] | Ratio per 100,000/year |
| 1938–1942 | 1 | 308 | 65 | 0 | 145 | 0 | 1 | 453 | 44 |
| 1943–1947 | 4 | 348 | 230 | 3 | 207 | 290 | 7 | 555 | 252 |
| 1948–1952 | 9 | 382 | 471 | 16 | 252 | 1,270 | 25 | 634 | 789 |
| 1953–1957 | 17 | 366 | 929 | 19 | 320 | 1,188 | 36 | 686 | 1,050 |
| 1958–1962 | 18 | 313 | 1,150 | 18 | 406 | 887 | 36 | 719 | 1,001 |
| 1963–1967 | 8 | 238 | 672 | 8 | 495 | 323 | 16 | 733 | 437 |
| 1968–1972 | 1 | 162 | 123 | 15 | 580 | 517 | 16 | 742 | 431 |
| 1973–1977 | 1 | 103 | 194 | 10 | 631 | 317 | 11 | 734 | 300 |
| 1978–1982 | 0 | 68 | 0 | 17 | 664 | 512 | 17 | 732 | 464 |
| 1983–1987 | 0 | 50 | 0 | 18 | 663 | 543 | 18 | 713 | 505 |
| 1988–1992 | 1 | 47 | 426 | 24 | 656 | 732 | 25 | 703 | 711 |
| 1993–1997 | 0 | 29 | 0 | 14 | 636 | 440 | 14 | 665 | 421 |

[a]Subjects alive are all subjects in our group alive during that 5-year period. Variations reflect the net effect of births and deaths during that period. Juveniles alive are all subjects who were <20 years of age in the middle of the period.

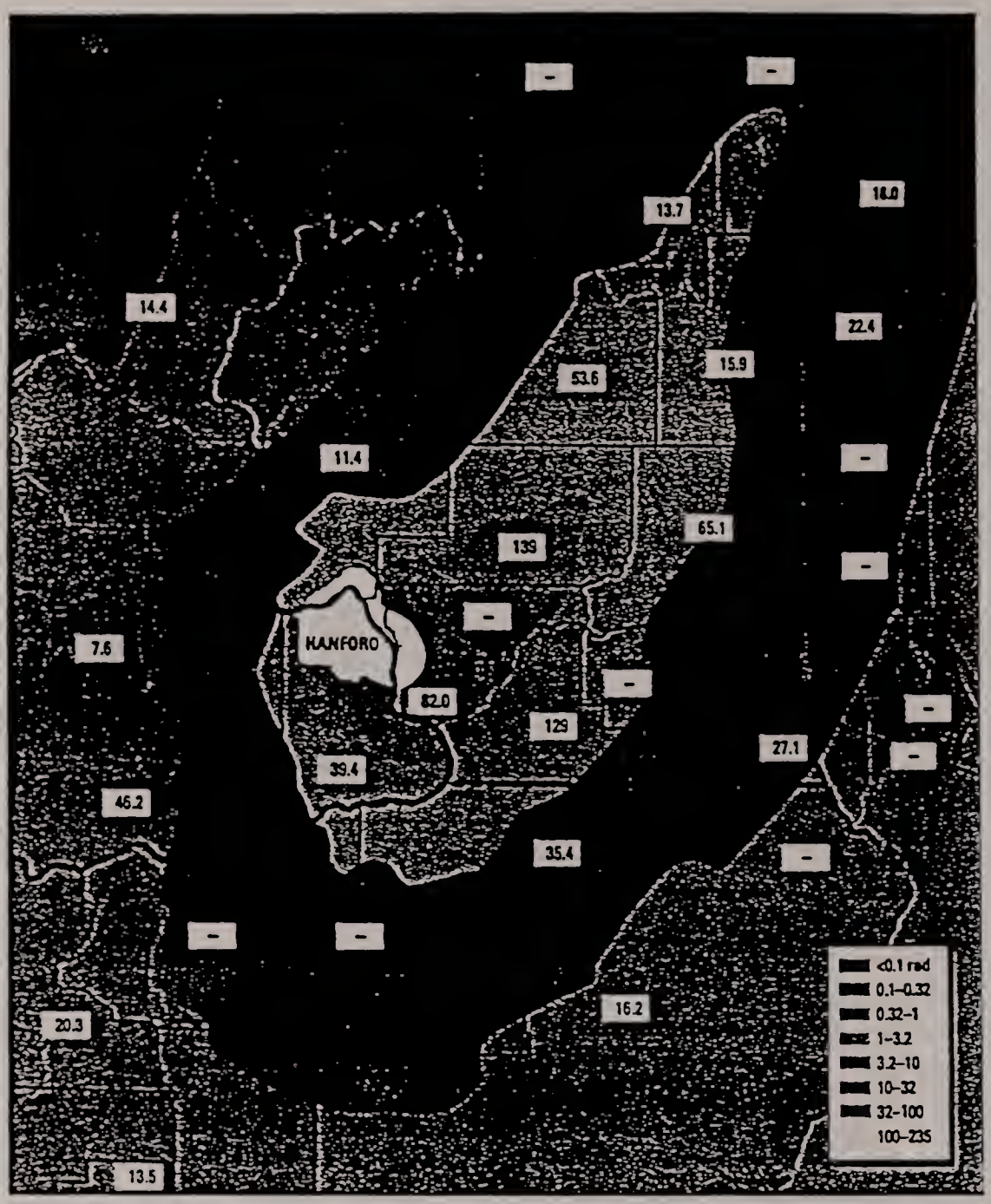


Figure 3. Isopleths of doses to the thyroid for a child (3) and ratio of self-reported cases of hypothyroidism per 100,000 population under 20 years of age in potentially exposed counties represented in the Hanford downwinder group (Table 3). A dash (–) in Table 3 and on the map indicates that we have no reported cases of juvenile hypothyroidism from these counties among our group of respondents.

Table 3. Self-reported cases of juvenile hypothyroidism by county in a group of Hanford, Washington, downwinders and ratios per 100,000 of county population <20 years of age (1950)

| State, county | No. of cases | Population <20 years of age | Ratio per 100,000 |
|---|---|---|---|
| Idaho | | | |
| Benewah | 0 | 2,253 | – |
| Bonner | 1 | 5,564 | 18.0 |
| Kootenai | 2 | 8,916 | 22.4 |
| Latah | 0 | 7,179 | – |
| Lewis | 0 | 1,610 | – |
| Nez Perce | 0 | 7,940 | – |
| Oregon | | | |
| Deschutes | 1 | 7,402 | 13.5 |
| Gilliam | 0 | 908 | – |
| Morrow | 0 | 1,703 | – |
| Umatilla | 5 | 14,131 | 35.4 |
| Union | 1 | 6,164 | 16.2 |
| Wallowa | 0 | 2,525 | – |
| Wasco | 1 | 4,917 | 20.3 |
| Washington | | | |
| Adams | 3 | 2,157 | 139 |
| Asotin | 1 | 3,691 | 27.1 |
| Benton[a] | 3 | 7,616 | 39.4 |
| Chelan | 2 | 13,892 | 14.4 |
| Columbia | 0 | 1,620 | – |
| Ferry | 0 | 1,651 | – |
| Franklin | 0 | 4,684 | – |
| Grant | 1 | 8,740 | 11.4 |
| Klickitat | 2 | 4,328 | 46.2 |
| Lincoln | 2 | 3,733 | 53.6 |
| Pend Oreille | 0 | 2,756 | – |
| Spokane | 11 | 69,257 | 15.9 |
| Stevens | 1 | 7,277 | 13.7 |
| Tri-Cities[b] | 13 | 15,852 | 82.0 |
| Walla Walla | 16 | 12,382 | 129 |
| Whitman | 7 | 10,750 | 65.1 |
| Yakima | 4 | 52,778 | 7.6 |
| Total, HEDR area[c] | 77 | 294,376 | 26.2 |

[a]Excluding urban areas of Kennewick and Richland.
[b]Urban areas of Kennewick, Pasco, and Richland.
[c]Data from the Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project (3).

*Chernobyl study population.* Table 4 shows the number of cases of hypothyroidism and rates per 10,000 for boys and girls for each of the five regional screening centers (5). The exposures in Gomel and Zhitomir were greater than those in Mogilev and Bryansk and lowest in Kiev (Fig. 4). The rates of hypothyroidism were appreciably higher in Zhitomir and Gomel, somewhat higher in Mogilev and Bryansk, and lowest in Kiev. The only exception was the female rate in Kiev, which was approximately equal to that in Mogilev.

Using data obtained from individual communities (Table 5), we first selected those communities with two or more cases of hypothyroidism of either sex and averaged the body burden estimates of $^{137}Cs$ for those communities in relationship to frequency of hypothyroidism. Because of its uniform availability and general stability, we chose to represent the body burden as the upper 75th percentile of the distribution. We included any community for which there were six or more body burden measurements. The exposure data per community are similar for boys and girls, yet the rates for girls are mostly higher than those for boys.

Figure 5 shows the relationship of body burden of $^{137}Cs$ with hypothyroidism for boys and Figure 6A and 6B show the same for girls. Figure 5 shows a correlation coefficient of 0.71, which is significant. For girls, even when the communities with exposures above a mean of 60 Bq/kg are omitted (Fig. 6B), the coefficient is only 0.35, which is nonsignificant.

## Discussion

Although the self-selected nature of the Hanford sample precludes any effort to estimate the rate of incidence of hypothyroidism in the population in general, the large number of cases, their apparent congruence with estimated but uncertain average doses to the thyroid for the counties of residence, and their onset shortly after massive emissions of $^{131}I$ suggest their description as an epidemic phenomenon related to emissions of $^{131}I$.

We recognize that a small cluster of cases could be the result of the diagnostic criteria of a single practitioner, but the spread of cases over a wide region makes this unlikely. Although knowledge of heavy exposure to radioactive emissions could have encouraged doctors to look for hypothyroidism, the massive emission of $^{131}I$ was not admitted by the government until 1986 and the diagnoses for the juveniles in our group had been made decades earlier. The link of juvenile hypothyroidism among Hanford downwinders with emissions of $^{131}I$ is supported by the apparent congruence of ratios of cases per 100,000 population <20 years of age and the rough estimates of thyroid doses for children when

the data are examined by county. If the age distribution of children who were living at the time of maximal emissions in 1945 are examined, most of them were exposed at <10 years of age. In fact, the only two children who were older than 10 years of age at the time of maximal exposure developed hypothyroidism very quickly in the years between 1945 and 1947.

The Marshall Island population exposed to the Bravo nuclear bomb test on 1 March 1954 also showed an unexpected development of hypothyroidism in children exposed prior to 10 years of age. According to Cronkite et al. (*8*),

> Anthropometric measurements...revealed that beginning a few years after exposure, some of the exposed children, particularly boys less than 10 years of age, lagged in growth. Growth deficiencies were the result of hypothyroidism and were corrected by thyroxin therapy.... In 1966 on the advice of a panel of thyroid experts the exposed Rongelap (later the Ailinginae) group were put on lifetime thyroxin therapy, in the hope of reducing the development of thyroid tumors.... The thyroxin treatment has not been completely successful. Some people on therapy developed tumors.

Although the marked excess of thyroid cancer in young children from the Chernobyl area is well known, little attention has been paid to the even greater increase in childhood hypothyroidism in this population. Because of its scope and standardization, the Chernobyl Sasakawa Health and Medical Project findings indicate that there is a significant association, at least for boys, with the range of exposures to $^{137}Cs$. For girls, there seems to be some protective mechanism for the upper levels (>60 Bq/kg) of exposure. Quastel et al. (*9*) have shown a significant shift in the TSH distribution toward higher TSH values for girls immigrating to Israel from the more heavily contaminated region of Gomel, as compared to those for girls emigrating from Kiev. However, any interpretation of a dose–response relationship must remain tentative, as current (1991–1996) levels of $^{137}Cs$ body burden cannot be expected to be closely related to the unmeasured radioiodine exposures in 1986. Not only is there no reliable estimation of thyroid dose available for these five regions, but the 5-year hiatus of observations from 1986 to 1991 makes it impossible to document the initial rise in frequency of hypothyroidism among the Chernobyl population, as was observed among our group of Hanford downwinders. Although the lack of these important data is unfortunate, the major strengths of the Japanese monitoring data are the study size, the representativeness of the samples, and the standardized approach.

**Table 4.** Juvenile hypothyroidism by region, community, and sex in the vicinity of Chernobyl (*5*)

| | Gomel | | Mogilev | | Bryansk | | Zhitomir | | Kiev | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Boys | Girls | Boys | Girls | Boys | Girls | Boys | Girls | Boys | Girls |
| Cases | 14 | 27 | 6 | 7 | 6 | 10 | 26 | 39 | 4 | 9 |
| Rate per 10,000 | 15.7 | 28.4 | 5.2 | 5.9 | 6.2 | 10.2 | 19.1 | 25.6 | 3.1 | 6.3 |

Gomel and Mogilev are in Belarus; Bryansk is in Russia; Zhitomir and Kiev are in Ukraine.

**Table 5.** Community rates (per 10,000) for hypothyroidism by sex, with estimated exposures in Chernobyl-affected regions (*5*) based on body burdens of $^{137}Cs$ (Bq/kg)

| Community (city or surrounding area) | Region | Rates | | Estimated dose | |
|---|---|---|---|---|---|
| | | Boys | Girls | Boys | Girls |
| Klintsy | B | 9.2 | 9.0 | 65.9 | 51.9 |
| Novozybkovskii | B | 0.0 | 14.6 | 172.7 | 141.7 |
| Remainder of Bryansk | B | (2.2)[a] | 4.8 | – | – |
| Zlynkovskii | B | 0.0 | 23.6 | 187.2 | 185.0 |
| Gomel | G | 32.5 | 22.7 | 38.4 | 37.5 |
| Gomelskii | G | 11.0 | 27.7 | 44.8 | 47.8 |
| Rechitskii | G | (11.6) | 56.7 | 43.0 | 50.4 |
| Remainder of Gomel | G | 13.9 | 24.6 | – | – |
| Borodyanskii | K | 0.0 | 20.0 | 39.4 | 39.1 |
| Brovarskii | K | 24.6 | 0.0 | 33.4 | 28.8 |
| Irpenskii | K | (3.5) | 6.8 | 30.5 | 31.8 |
| Svyatoshinskii | K | 0.0 | 23.8 | 25.9 | 23.7 |
| Mogilev | M | (1.8) | 3.5 | 28.3 | 29.1 |
| Mogilevskii | M | 13.3 | (6.8) | 30.7 | 30.1 |
| Remainder of Mogilev | M | 4.8 | 4.6 | – | – |
| Slavgorodskii | M | (36.2) | 69.7 | 71.8 | 47.7 |
| Emilchinskii | Z | 19.8 | 33.8 | 69.0 | 52.1 |
| Korosten | Z | 8.1 | 20.1 | 43.5 | 39.9 |
| Korostenskii | Z | 28.5 | 18.5 | 59.0 | 56.3 |
| Luginskii | Z | 27.2 | 63.5 | 105.7 | 106.2 |
| Malinskya | Z | (8.8) | 49.8 | 40.0 | 38.2 |
| North Volinskii | Z | (6.2) | 23.3 | 36.4 | 34.6 |
| Olevskii | Z | 36.6 | (7.5) | 131.8 | 99.1 |
| Ovruchskii | Z | 56.1 | 39.7 | 117.4 | 83.3 |

Abbreviations: B, Bryansk; G, Gomel; K, Kiev; M, Mogilev; Z, Zhitomir.
[a]The data shown in parentheses are based on a single case.

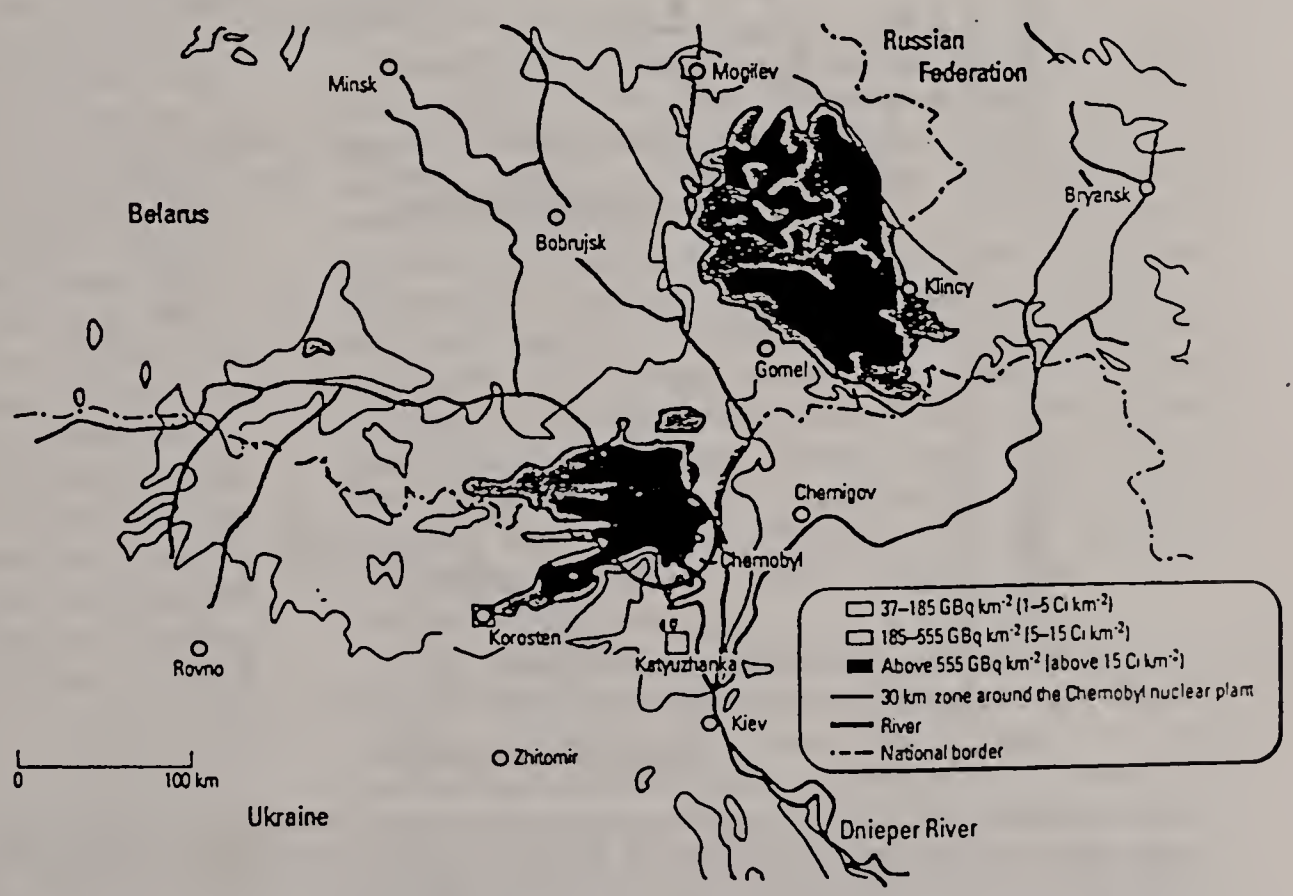


**Figure 4.** Isopleths of $^{137}Cs$ surface contamination in regions around Chernobyl. Adapted from the International Advisory Committee (*7*).

The upper normal limits of serum TSH used to define hypothyroidism for the Chernobyl children (*5*) seem somewhat lower than those generally used clinically. On the other hand, no laboratory data were available for the group of Hanford downwinders.

We believe that these Hanford and Chernobyl data, along with the data from the Marshallese study (*10*) and the increase in thyroid autoantibodies found among children and adolescents from Belarus following the Chernobyl accident (*11*), suggest that screening tests for juvenile hypothyroidism can be beneficial among populations exposed to radioiodine.

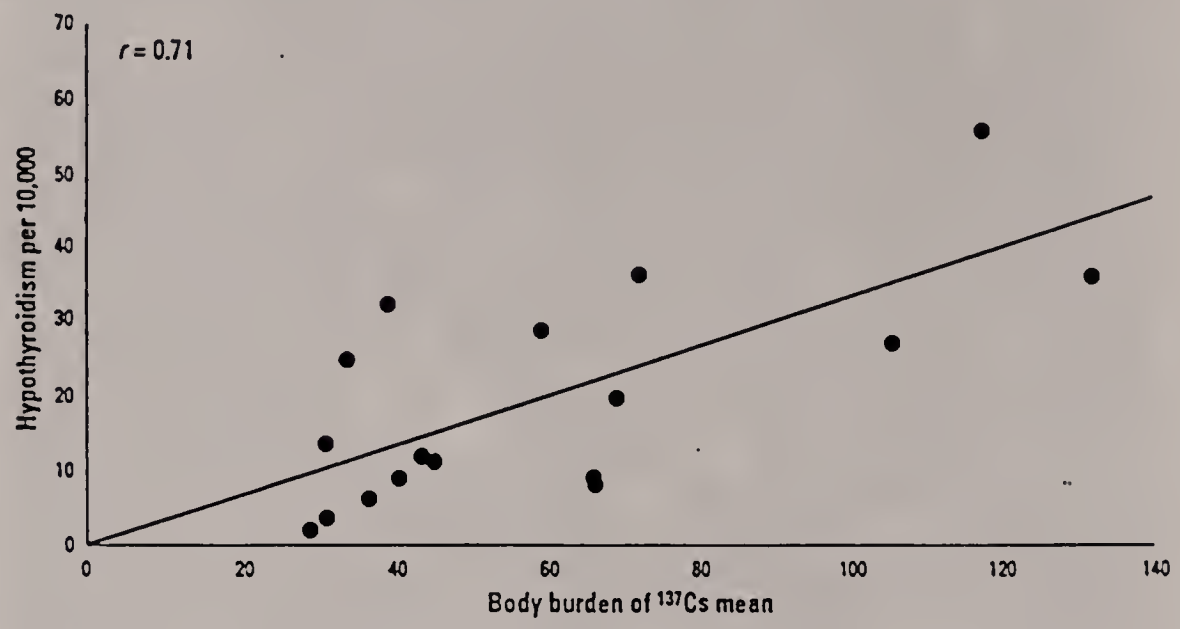


Figure 5. Association of mean $^{137}Cs$ body burden with hypothyroidism per 10,000 for boys near Chernobyl, by community. $^{137}Cs$ is the mean of 75th percentile for all ages and all years with six or more cases observed.

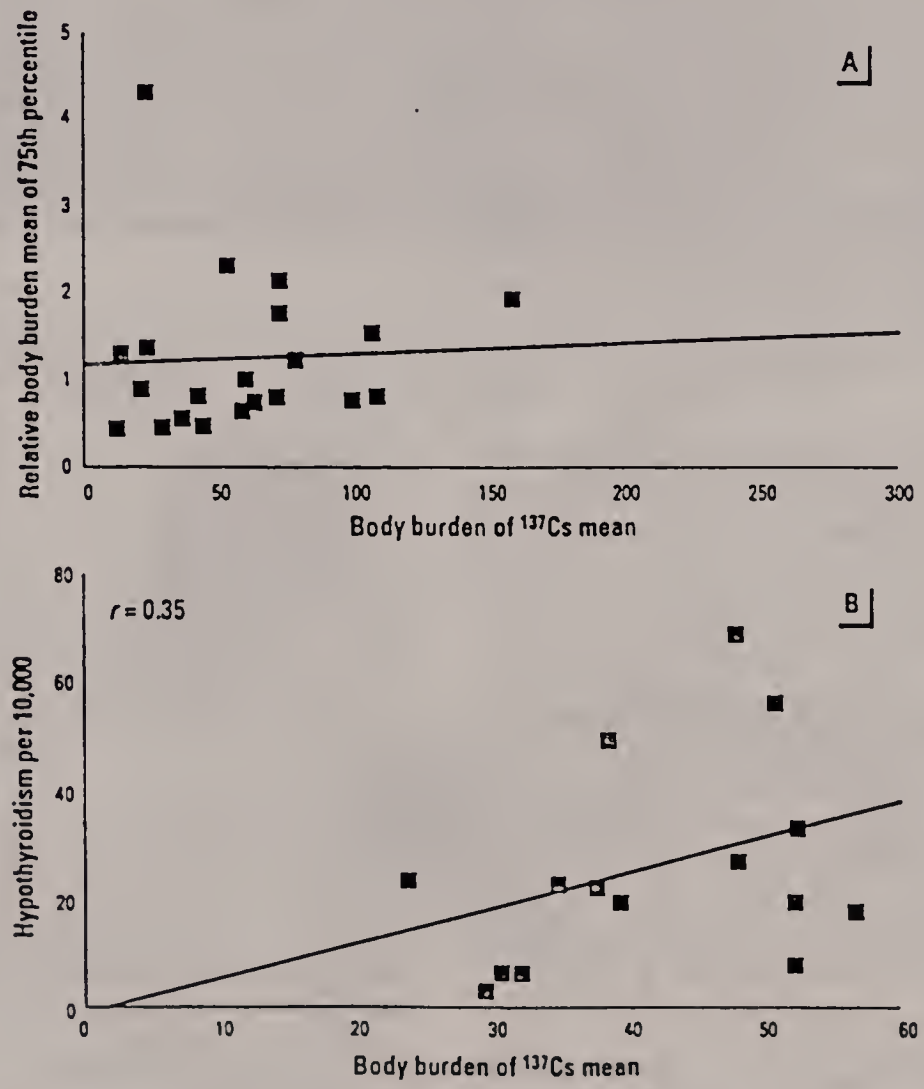


Figure 6. (A) Association of $^{137}Cs$ body burden rate with hypothyroidism for girls from communities with >1 case of hypothyroidism near Chernobyl (rate per 10,000), all regions. The relative body burden is the mean of the 75th percentile. (B) Association of mean $^{137}Cs$ body burden <60 Bq/kg with hypothyroidism for girls near Chernobyl (rate per 10,000). $^{137}Cs$ body burden is the mean of 75th percentile for all ages and all years with six or more cases measured.

## Conclusion

The massive emissions of $^{131}I$ in 1945 from the Hanford plutonium manufacturing plant appear to be associated with the subsequent occurrence over the next 20 years of an epidemic of juvenile hypothyroidism among children living downwind. There is general congruence of the estimated cumulative thyroid dose and the numbers of cases per 100,000 juveniles by counties. In 1945, most of the children were younger than 10 years of age. The finding of a community rate associated with exposure for children living near Chernobyl suggests that for any community with large radioiodine exposures, hypothyroidism in children is a likely occurrence, and if found, it can easily be treated. Therefore, screening tests may be beneficial for such populations.

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# Hypothyroidism and Spontaneous Abortions among Hanford, Washington, Downwinders

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ABSTRACT. Spontaneous abortions occurred more than twice as frequently in hypothyroid women, compared with nonhypothyroid women. Both groups of women had lived in the same environment during the same period of time. The high incidence of hypothyroidism in a cohort of several hundred women who lived downwind of the Hanford, Washington, nuclear installation was likely associated with environmental contamination from deliberate releases of radioactive iodine from the facility.

IN A REVIEW published in 1991,[1] Lowe et al. stated that "overt hypothyroidism complicating pregnancy is uncommon probably because it is associated with infertility." No mention of spontaneous abortion appeared in that review. In 1989, Speroff et al. stated that "thyroid problems are no longer considered reasons for recurrent abortion," but in the authors' 1994 edition[2] the following statement is found: "There is also reason to believe that patients with hypothyroidism have an increased rate of spontaneous abortion." Other researchers have indicated that increased numbers of abortions appear to be linked with hypothyroidism.[3,4]

In this study, several hundred women (*downwinders*) were surveyed by questionnaires. Downwind was defined as the intermountain area between the Cascade and Rocky Mountain ranges in Oregon, Washington, and Idaho. The occurrence of spontaneous abortion among those women who had been told that they had hypothyroidism was twice that of women who were not hypothyroid. The data obtained from the survey questionnaires are described in this study. Also provided is a brief review of the literature that describes the relationship between spontaneous abortion and hypothyroidism.

## Method

Questionnaires were sent to several hundred women who lived in the intermountain area between the Cascade and Rocky Mountain ranges in Oregon, Washington, and Idaho (i.e., downwinders). Information was solicited about their health histories. The number of spontaneous abortions, the number of women who had been told by a physician that they had hypothyroidism and were taking thyroid medication were tabulated. No diagnostic biochemical information was available, and we did not have information about whether the women took thyroid medication during pregnancy. Stillbirths and congenital deformities were also tabulated, but the numbers were mini- mal. Women who had thyroidectomy after menopause were included in the nonhypothyroid category.

Large quantities of radioactive iodine ($^{131}I$) were released deliberately from the Hanford, Washington, nuclear installations on at least two occasions. It is well known how this radioisotope enters the food chain, especially milk. Other radioactive iodine isotopes—some with longer half-lives—were likely mixed with the documented incidents of $^{131}I$ releases, but there was no reli-

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able information about their contribution to internal doses among the downwind population. This was also true for environmental contamination from other radioactive isotopes or hot particles.

## Results

A total of 147 hypothyroid women reported that they had experienced 84 spontaneous abortions, compared with a total of 188 nonhypothyroid women, among whom 38 spontaneous abortions had occurred. The difference between the two groups was very significant ($p < .001$). If we were to exclude the nonhypothyroid women who were euthyroid, but who had thyroid nodules or cancer of the thyroid, and women with hyperthyroidism, the difference in the incidence of miscarriages would have been even greater.

## Discussion

Longcope[3] mentioned in his study that spontaneous abortions occurred during the first trimester in hypothyroids. Thomas and Reid[4] referred to an increased incidence of spontaneous abortions in hypothyroids, but Davis et al.,[5] who described 16 complicated pregnancies in hypothyroids, did not mention miscarriages. During the 1960s, Jones and Man[6] reported a significantly higher rate of spontaneous abortions among women who had below-normal butanol-extractable iodine levels, compared with normals. Stagnaro-Green et al.[7] demonstrated a definite association between an increase in thyroid autoantibodies in the first trimester and an increased rate of miscarriage, even though only 2 of 17 autoantibody-positive women had chemical hypothyroidism. In 1992, Maruo et al.[8] reported 11 spontaneous abortions in women who had significantly lower T3 and T4 levels, compared with 21 who did not miscarry.

The questionnaires that we evaluated were obviously those returned to us. A small percentage of the respondents had no medical problems; perhaps the persons with complaints were more likely to respond. We are aware that this study was not designed according to standard epidemiological criteria. Nevertheless, the significant difference between the hypothyroids and the nonhypothyroids in our cohort of downwind women indicated an association among environmental exposures to radioactive iodine, hypothyroidism, and subsequent miscarriages. There were other anomalies in this cohort (e.g., prevalence of cancers versus cardiovascular disease) that will be reported at some future time.

Perhaps the most striking statistic of all in our survey was that approximately one-half of the women who responded had hypothyroidism. It is difficult to think of any cohort of women anywhere with such a high percentage of hypothyroids, except for a thyroid clinic in a teaching center. This emphasizes the damage that most likely occurred from deliberate or accidental releases of radioactivity and its subsequent fallout.

* * * * * * * * * * *

The authors thank members of Northwest Radiation Health Alliance (NWRHA) Lois Camp, Pat Hoover, Barbara Howard, Linda Keir, Sharon Lee, Laureen Nussbaum, Mary Pengelly, and Kay Sutherland for their assistance in distributing, collecting, and analyzing the questionnaires. Appreciation is also expressed to Judith Jurji for her contribution of questionnaires that were collected by her from members of the Hanford Downwinders Coalition.

This study was supported, in part, by a grant from the MacKenzie River Gathering Foundation to NWRHA, and it was assisted by the Portland Chapter of Physicians for Social Responsibility.

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**Updated Female Hypothyroidism and Adverse Birth Outcomes (1998)**

| Hypothyroid: 210 | | | Non-Hypothyroid: 308 | |
|---|---|---|---|---|
| | | Rate/Fem | | Rate/Female |
| Miscarriages | 129 | 0.61 | 92 | 0.30 |
| Stillbirths | 24 | 0.11 | 15 | 0.049 |
| Low Birthweight | 17 | 0.081 | 13 | 0.042 |
| Other Adversities | 43 | 0.20 | 54 | 0.18 |

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Commissioner

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August 24, 1998

Hon. Edward F. Jacoby, Jr.
Chairman
NYS Disaster Preparedness Commission
Building #22 - The State Campus
Albany, New York 12226-5000

Dear Mr. Jacoby:

This is to recommend that the New York State policy on the prophylactic use of potassium iodide (KI) by the public during severe nuclear power plant emergencies be revised unless there are compelling logistical or legal reasons for maintaining the current policy.

The current NYS Radiological Emergency Plan adopted by the NYS Disaster Preparedness Commission in 1983 sets the state policy on the prophylactic use of KI as a thyroid blocking agent during a severe nuclear power plant emergency. The policy recommends that KI use be limited to emergency responders and institutionalized individuals who cannot be evacuated in time. Under this policy, KI will not be recommended for use by the public.

A number of factors contributed to the current policy. Some of these factors were based on health considerations, while others considered logistical questions of stockpiling and distribution. Two health related arguments that weighed heavily in arriving at the 1983 policy were:

- Evidence from studies of patients given radioiodine for thyroid disease indicated radioiodine effectiveness for producing radiogenic thyroid cancer to be low, and

- Little information was available on the risk of allergic reactions to KI, and there was concern that the risk of side effects will exceed the protective benefits of using KI.

New information on both issues became available recently from studies following the Chernobyl accident. As a result, we have asked the Department's Radiological Health Advisory Committee to assist us in reviewing the new information and the health implications of using KI for public protection during emergencies. The Committee reviewed these issues in its meeting held in Albany on November 21, 1997. The Committee's conclusions are:

- There is significant evidence that radioactive iodine has caused cancer of the thyroid among exposed children in Belarus, Ukraine and Russia.

- The use of potassium iodide is effective in reducing the thyroid dose if given before or shortly after exposure.

- The extensive use of KI in many over the counter drugs and in medicine, and its wide distribution in Poland following the Chernobyl accident, indicate that the risk of serious side effects from potassium iodide is very small.

Based on these findings, the Committee saw no health related reasons why KI should not be provided to the general public, and recommended that KI use be one of the options available for public protection in an emergency.

While the health related concerns that led to the current NYS policy on KI appear to have been addressed by the new data, questions relating to the logistics of storage and distribution of KI remain to be considered. These, and similar issues, are best examined by a panel in which the different interested or affected parties are represented. In addition to state agencies, this includes county governments, nuclear power plant operators and public representatives. The issues that we believe need to be addressed by such a panel include:

- Feasibility of, and methods for assuring that KI will be available to users in time to be effective in reducing radioiodine uptake by the thyroid;

- Methods for assuring the timely replacement of KI when shelf life has expired;

- Public information program advising users on benefits, limitations and risks of KI use;

- Identification of responsible parties for implementing the different actions associated with changes to the current policy; and

- Examination of the legal liabilities that may be associated with the policy change.

The recommended review of the KI policy is also consistent with the anticipated federal requirement that states consider the use of KI when preparing their emergency response plans.

Since the State Emergency Management Office has responsibility for the state's emergency response plans, we recommend that your Office take the lead in forming the panel which reviews the KI policy and coordinating its activities. Department staff are available to assist you with this endeavor.

Very truly yours,

Barbara A. DeBuono M.D.

Barbara A. DeBuono, M.D., M.P.H.
Commissioner of Health

# Background Paper on the Use of Potassium Iodide During Nuclear Reactor Emergencies : Health Considerations

## Introduction

There are six operating nuclear power plants in New York State. The reactors contain large amounts of different radioactive materials that are produced during normal reactor operation. While the reactors are normally designed with redundant engineered safety systems and built with multiple barriers to prevent the escape of these materials to the environment, a considerable emergency planning effort has been undertaken in NY to mitigate the consequences of an accident that could lead to the release of large quantities of radioactive materials from any of these plants.

If a large amount of radioactive materials is released in a reactor accident, radiation exposure to the public may occur through a number of exposure pathways. These pathways include exposure to the plume escaping from the reactor, ground contamination and the ingestion of contaminated water or food products. The relative contribution to the total dose from these pathways varies depending upon the type of radioactive materials released, meteorological conditions and the nature and effectiveness of any protective measures implemented to prevent or reduce public exposure. Radioactive isotopes of iodine are normally present in large quantities in the reactor. If released, iodine isotopes can be inhaled by those present in the plume. Iodine that deposits on the ground is readily incorporated into milk and vegetables and can form a significant potential source of public radiation exposure. As iodine is taken up by the thyroid, radioactive iodine entering the body through inhalation or ingestion can lead to large doses to the thyroid.

Emergency response plans, during the initial phase, focus on providing public protection from exposure to the plume. The emergency response plans provide for the timely notification of authorities and the public. They also set levels of potential radiation doses which, if exceeded, would trigger actions to protect public health. The plans adopt the concept that

during the early phase of the emergency, when the plume is the primary source of exposure, public protection is to be accomplished through evacuation from affected areas. Where evacuation is associated with greater risk than remaining in place, due to weather or other conditions, sheltering in place can be used to provide protection. Sheltering may also be used as the protective measure of choice in the case of a limited or a controlled release of radioactive materials.

The intake of stable iodine, in the form of potassium iodide (KI), can be used as a third protective alternative to reduce the dose from inhaled radioiodine isotopes. When taken before or shortly after exposure to a radioactive plume containing radioiodine, KI acts to block or reduce the uptake of the radioiodine by the thyroid gland. This significantly reduces the radiation dose to the thyroid, as well as the component of the whole body dose resulting from radioactive iodine. The use of KI, however, does not reduce the radiation doses received from noble gases and radioactive materials, other than radioiodine, that can be released in an accident. The current NY State emergency response plan recommends the use of KI for emergency responders and populations of certain facilities that cannot be evacuated in time, but not for the general public.

Information that became recently available on the risk of childhood thyroid cancer following the Chernobyl accident in 1986, and the information on the risk of side effects following the mass administration of KI for prophylactic use in Poland were reviewed by the Department's Radiological Health Advisory Committee. The Committee found no public health reason for continuing the current NY State policy on KI use for the general public. The Committee also recommended that, besides evacuation and sheltering, NY should consider making the option to use KI one of the public protective measures during a severe nuclear power plant accident.

**Effect of Radioiodine on the Thyroid**

Iodine enters the blood stream rapidly following inhalation or ingestion [ICRP 1995]. It can

also be absorbed through the skin. Of the iodine entering the blood stream between 10% to 40% is taken up by the thyroid, with the average uptake assumed to be 30%. Iodine is removed from the blood serum with a half life of about 5 hours. Once in the thyroid, the iodine is eliminated with a half life ranging from 40 - 120 days. The uptake fraction and residence time of iodine in the thyroid strongly depend on the thyroid function. The radiation dose to the thyroid that results from the intake (inhalation or ingestion) of a certain amount of radioiodine depends on the thyroid mass and function. The dose per unit intake, thus, varies with the age of the exposed individual, generally increasing with younger age.

Iodine passes the placenta freely. The dose to the fetal thyroid depends on the stage of development of the fetal thyroid and its function. The fetal thyroid begins to concentrate iodine beginning at the 12th week of gestation. The fetal thyroid dose per unit of radioiodine intake by the mother reaches a peak value if the intake occurs during the 19th week of gestation. At this point, the dose to the fetal thyroid is about twice the dose to its mother's thyroid [NRC 1992].

Thyroid irradiation may lead to a number of health effects. These include hypothyroidism, benign nodules and thyroid cancer [Williams 1996]. The carcinogenicity of radiation has been established in a number of epidemiological studies of patients who received x-ray treatment for a number of benign head and neck diseases. The findings of these studies were also consistent with the increased thyroid cancer among the Japanese bomb survivors who received external doses from gamma and neutron radiation. The studies also established that children are at a greater risk of radiation induced thyroid cancer than adults [Becker 1996, Williams 1996]. The risk from external radiation is estimated to be 4.4 excess cancers per million per rad and the excess relative risk is 0.077 per rad [Ron 1995]. The risk following thyroid irradiation at the ages of five years or less is five times that for older children and about eight times the risk for young adults. The relative risk of cancer induction for females is about two to three times that in males [Becker 1996]. Radiogenic thyroid cancers among children are observed after a latency period of about 5-10 years and the increase in risk persists for decades following

radiation exposure [Williams 1996].

Studies of patients who were given I-131 for treatment did not show evidence of increased thyroid cancer risk [Becker 1996]. A report issued in 1985 by the National Council on Radiation Protection and Measurements (NCRP) found that existing data suggest that I-131 is less effective than external dose in inducing thyroid cancer and gave the risk estimate for I-131 to be equal to one third of that of x-rays [NCRP 1985]. The lower dose rate and the different dose distribution were given as probable reasons for the lower effectiveness of I-131 when compared to x-rays.

A report prepared by the US Nuclear Regulatory Commission staff indicates that preliminary epidemiological studies following the Chernobyl accident show that the risk factor for thyroid cancer induction from internally deposited radioactive iodine may be similar to that from external radiation [NRC 1998a].

**Thyroid Cancer in Populations Exposed to Radiation Following the Chernobyl Accident**

Increased childhood thyroid cancer in areas that received fallout of radioactive materials released in the Chernobyl accident was observed as early as 1990, four years after the accident. The data on thyroid cancer observed among children in Belarus, Ukraine and Russia were reviewed in 1996 by Becker et al [Becker 1996] and by Williams et al [Williams 1996]. The relevant observations can be summarized in the following:

- In the ten years following the Chernobyl accident, more than 1,000 childhood cancers were reported in the areas of Belarus, Ukraine and Russia that received the highest exposure. Pathological diagnoses of the cases reported in some of the studies have been confirmed in more than 90% of the cases.

- The risk of thyroid cancer is seen to increase with decreasing age at exposure.

This is consistent with the age at exposure dependence observed for external radiation.

- There is a strong correlation between the increase in thyroid cancer incidence rate and the radioactive material fallout from Chernobyl.

- Temporal evidence shows that the increased risk drops dramatically in children born more than 6 months after the Chernobyl accident. This is consistent with an increased risk associated with this accident.

- Screening is not believed to have contributed significantly to the number of observed cases.

- Available data, thus far, do not allow the derivation of risk estimates due to doses from radioiodine intake.

- Questions remain as to the possible contribution to the observed risk of genetic factors and iodine deficiency in the diet of the affected population.

**Potassium Iodide as a Thyroid Blocking Agent**

The US Food and Drug Administration announced its final recommendations on the use of KI to the general public in a radiological emergency in 1982 [FDA 1982]. FDA recommended that the use of KI be considered in emergencies where the projected radiation dose to the thyroid gland from radioiodine is 25 rad or greater. FDA recommended a daily KI dose of 130 mg for adults and children above one year of age. For children one year of age or less, a KI dose of 65 mg per day was recommended.

To have the greatest effect in decreasing the uptake of radioiodine by the thyroid gland, these

doses of KI should be administered immediately before or after exposure. KI given with radioactive iodine results in a 97% block of the radioiodine uptake by the thyroid [Becker and Zanzonico 1997]. Uptake is blocked by 90% if KI is administered 12 hours prior to exposure. The blocking efficiency of KI is reduced to 85% if taken one hour after exposure, to 50% at 3 hours and 5-10% at 6 hours.

**Adverse Reactions to KI**

Consideration of potential adverse reactions to mass use of KI, was one of the reasons why the current NY State policy on use of KI states that it will not be used for the general public. When the policy was developed in 1983, uncertainties existed as to the incidence and severity of side effects from KI [FDA 1982]. Information now available on reactions to cough syrups and expectorants that contain KI give an estimate of 1 in 10,000,000 for the incidence of adverse reactions from a daily dose of 130 mg of KI [NRC 1995]. Further information on KI side effects comes from the experience in Poland following the Chernobyl accident where KI was widely distributed to the population with minimal serious adverse reactions reported. About 18 million doses of KI were distributed in Poland, of which about 10,500,000 doses were given to children and 7,000,000 to adults. It is estimated that 95.3% of children and 23% of the adult population in Poland were given one or more doses of KI.

A follow-up study of about 12,000 children and 5,000 adults showed that 4.6% of the children and 4.5% of the adults had side effects. Among children 2.4% had vomiting, 1.1% skin rashes, 0.4% stomach pain. Among adults 1.2% reported skin rashes, 0.9% vomited, 0.7% complained of headaches, 0.6% had stomach pain and 0.6% had shortness of breath. Two adults with chronic lung disease and known sensitivity to iodides developed acute respiratory distress which required hospitalization [Nauman and Wolff 1993].

In addition transient acute reactions were seen in 0.37% of newborns who received KI on the second day of life, where transient increase in the thyroid-stimulating hormone(TSH) and

decrease in the thyroid hormone thyroxine(T4) were seen.

**Recent Changes to Federal Policy on KI**

The US NRC announced recently that it intends to amend its emergency planning to require that "as each state develops the range of protective actions, consideration be given, as a supplement to evacuation and sheltering, to the use of potassium iodide, as appropriate" [NRC 1998b]. This position is a change from the current NRC policy which recommends that KI be stockpiled and distributed to emergency workers and institutionalized persons, but does not recommend its stockpiling or distribution for the general public.

The NRC announcement also indicates that NRC will work with other federal agencies to make a national KI stockpile available for use by states in the event of a severe nuclear power plant, or any other radiological emergency in which such use is appropriate. The federal government would also fund the purchase of KI by any state that wishes to have its own source.

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July 20, 1998
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STATE OF MAINE
Department of Human Services
Advisory Committee on Radiation

JAN 1997
Received

January 16, 1997

Dr. Dora Anne Mills, Director
Bureau of Health
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Dear Dr. Mills

This letter is to convey the recommendations of the Advisory Committee on Radiation regarding the distribution of potassium iodide to the general public. The Committee recommends that potassium iodide be available to the general public in the event of a nuclear emergency. The Committee also recommends that the distribution be done through established reception centers.

Below we have listed the reasons for creating and maintaining a stockpile of potassium iodide:

1. We know from Chernobyl and Windscale (England) that radioiodine can be a major part of the releases in nuclear facility accidents.

2. Iodine sequesters in the thyroid gland, with a very high enrichment and radioiodine causes dose to the thyroid.

3. Projected doses to the thyroid from severe reactor accidents would cause an increased incidence of thyroid diseases, including benign nodules and cancers. Hypothryoidism is also likely, leading to gradual insufficiency of thyroid hormones. Children and pregnant women are at greater risk.

4. Experience in Poland with potassium iodide given to preload the thyroid gland showed significant dose reduction to the thyroid, and few adverse reactions with 18,000,000 receiving one or more doses.

5. Potassium iodide is an inexpensive and useful accessory to radiological response. Potassium iodide has been demonstrated to be effective in minimizing the dose burden to the thyroid, thereby reducing the overall health detriment.

6. Existing guidance has created a double standard for radiation protection. When potassium iodide is recommended for the emergency workers near an accident, it should also be available to children, pregnant women, persons unable to evacuate, contaminated

persons and as many of the general public as seems practical to reduce any radioactive thyroid dose.

Therefore, the Committee recommends that

1. Potassium iodide should be made available at reception centers for evacuees in the event of observable contamination when screened, or when there is a potential for exposure based on other considerations, such as pathway(s) of exposure shown by models, or by travel path of evacuation or by ingestion.

2. Maine has the potential for radio-iodine contamination from nuclear facilities: Point LePreau in New Brunswick, Canada; Maine Yankee, Seabrook Station in New Hampshire, and the Portsmouth Naval Shipyard in Kittery, and in the vicinity of hospitals and airports where Iodine- 131 is shipped or used. (Hospitals use 1 to 200 millicuries for treatment). The State needs potassium iodide available for use in accidents in all these areas.

I would be pleased to discuss this matter with you at your convenience. I can be reached at 581-1018.

Sincerely

C. T. Hess

Charles T. Hess, Ph.D., Chairman
Advisory Committee on Radiation

cc: Bob Schell, Manager, Radiation Control Program
Phil Haines, Maine Bureau of Health
Uldis Vanags, State Planning Office
Bill Libby, Maine Emergency Management Agency
Committee Members

Maine Department of Human Services
Advisory Committee On Radiation
January 9, 1997

# Background Paper on Prophylactic Use of Potassium Iodide during Nuclear Emergencies

## I. Introduction

Potassium iodide, KI, is a thyroidal blocking agent developed for use during nuclear accidents wherein radioactive forms of iodine may be released. In 1975, the Reactor Safety Study projected that large releases of radioactive materials, including iodine, were possible for certain accident scenarios for civilian nuclear power reactors. Shortly after, the National Council on Radiation Protection and Measurements issued a report, NCRP 55[1], examining the efficacy and contraindications of thyroidal blocking agents. The Food and Drug Administration followed with a request for New Drug Applications, soliciting an application for a thyroidal blocking agent. An oral dosing form of potassium iodide was approved by the FDA in 1980. The FDA then issued recommendations for use, followed by development of the federal policy on distribution in 1985[2].

The State of Maine adopted the federal policy in 1987. That policy directed that KI would be distributed to emergency workers and made available to institutionalized individuals as needed during a nuclear accident. Emergency workers are provided potassium iodide as part of a 'dosimetry kit' and are instructed to take KI only when directed by the State Bureau of Health. Small stockpiles, (≦100 14-dose bottles) are maintained at the State and local county emergency management agencies for distribution to institutionalized individuals that may be delayed in evacuating with the general public. Emergency planning for the general public does not include use of potassium iodide, but relies wholly on timely evacuation and/or sheltering to avoid or reduce dose.

Recently, a Wiscasset area resident requested that the State review the existing policy for use of KI, with the specific request that KI be distributed for school children. The request was referred to the Advisory Committee on Radiation. The Committee held two meetings to discuss the issue. The first meeting held October 18 provided background material, provided a forum for open discussion which included public members and identified follow-up items. The Committee held a final discussion on December 6, 1996.

The Committee voted to recommend that potassium iodide be made available to the general public through established reception centers. The Committee did not believe that distribution to individuals was of any additional benefit, given the uncertainty of distribution and availibility. Also, the Committee recognized the special nature of children but did not believe that distribution to schools was advantagous or necessary at this time.

## II. Thyroid Physiology

The thyroid is a small, butterfly shaped gland, with two lobes positioned on either side of the trachea. Thyroid tissue is characterized by spherical follicles, formed by epithelial cells around a luminar space. Iodine is actively removed from the circulating blood serum by an 'iodide pump'. Uptake of serum iodide ranges from 25 to 90%, depending upon availability of iodide in the diet. In the US, an adult has an average intake of 225 micrograms of iodide per day, with 50 to 60 micrograms taken up by the thyroid[3].

Within the thyroid, the iodide is bound to tyrosine to form the hormones thyroxine and triiodithyrine. The hormones are released in response to thyroid stimulating hormone, TSH, released by the pituitary gland. TSH also controls the rate of iodide uptake, and hormone synthesis. The thyroid hormones control basal metabolic rate. The thyroid will release from 60 to 100 micrograms of thyroid hormone/day. However, though release is approximately equal to intake, a large store of iodine is kept in the thyroid, bound to colloid within the lumen of the follicles, so that the biological half-life for iodide in the thyroid ranges from 40 to 120 days, with 80 days being the average for an individual with sufficient dietary iodide intake.

Behavior of the fetal thyroid is a function of gestation period. Iodide freely passes the placenta from maternal to fetal circulation. The fetal thyroid will begin concentration of iodide at 12 weeks, synthesis of bound

iodide begins at approx. 19 weeks. The iodine, as thyroid hormone, is not actively released from the thyroid until 28 weeks. This corresponds to the time at which the fetal pituitary gland begins to release TSH.

The kidneys remove iodide at a rate slightly higher than the thyroid. The combined removal mechanisms lead to a serum half-life of iodide of approximately 5 hours. For an adult given a bolus of iodide, 10 to 40% will accumulate in the thyroid, with the greatest rate of uptake occurring in the first 10 to 12 hours. An additional 1 to 2 percent will be taken in from 12 to 24 hours after the initial exposure. This figure is shown in attachment 1.

Metabolic data for iodine from ICRP 30 indicates that the iodine is rapidly absorbed in the gastrointestinal tract, primarily in the small intestine. Iodine is also rapidly absorbed through the lungs. The uptake fraction for both ingestion and inhalation is 1.0. Once absorbed, 30% is assumed to be absorbed by the thyroid, with the remainder being excreted.

III. Thyroid Diseases

The thyroid may develop conditions of hypo or hyper thyroidism, benign nodules, adenomas, and cancers. These conditions all have a spontaneous incidence within the population and may also occur as a result of radiation exposure.

Hypothyroidism is the depression of thyroid hormone production with resultant slowing of the body's metabolism. In adults, this manifests as cold intolerance, fatigue, and weight gain. Hypothyroidism in children causes a reduction in skeletal maturation and prevents full body growth. Fetal hypothyroidism may cause profound effects in development and growth, including the central nervous system.

Hyperthyroidism is the overproduction of thyroid hormones with resultant speeding of the body's metabolism. This manifests as heat intolerance, fatigue and weight loss.

Nodules, including adenomas, are abnormal growths of thyroid tissue. Typically, these are benign, with no associated symptoms and are often undetected. Large nodules may cause discomfort, visible enlargement of the neck, and tracheal compression. A small number of thyroid nodules will produce thyroid hormones uncontrollably leading to hyperthyroidism. These may be treated surgically, or by therapeutic doses of radioactive iodine. Adenomas are new growths of thyroid tissue and may or may not actively produce hormones.

There are four thyroid cancer types: papillary, follicular, medullary and anaplastic. Nearly 80% of all thyroid cancers are papillary. Papillary tumors metastasize early to lymph nodes in the neck and may metastasize to nearby muscle and to the lungs. 10 year survival is about 90%. Follicular tumors occurs less frequently and tend to metastasize early to lung and bones. The 10 year survival rate for follicular tumors is about 50%. About 10% of all thyroid cancers are fatal[5].

IV. Radiogenic Effects

Radiogenic effects occur from external and internal irradiation of the thyroid. External radiation is considered to be about 3 times more effective for the induction of cancer when compared to a similar dose from radio-iodine (principally I-131). External radiation is considered to be about 5 times more effective than internal exposure for induction of thyroid nodules and hypothyroidism. This reduced effect is thought to result from differences in dose rate and dose distribution. Also, the thyroids for children and adolescents are assumed to be twice as sensitive to radiation when compared to adults[6].

Effects associated with radiation exposure are acute thyroiditis, hypothyroidism, and induction of benign and cancerous tumors. Risk estimates for these effects are given in Table 1, non-stochastic effects and Table 2 stochastic effects.

Table 1. Non-Stochastic Effects of Radiation Exposure

| Effect | Threshold Dose (Rad) | Risk |
|---|---|---|
| Acute radiation thyroiditis | 20,000 | estimated that for each 10,000 Rad increment above 20,000 5% of exposed individual s will develop thyroiditis |
| Hypothyroidism | 1,000 (internal)<br>200 (external) | 17 per $10^6$ persons per Rad<br>83 per $10^6$ persons per Rad |

Source: NUREG/CR-6310

Table 2. Stochastic Effects of Radiation Exposure

| Effect | Exposure source | Persons over age 18 at time of exposure* | | Persons under age 18 at time of exposure | |
|---|---|---|---|---|---|
| | | Male | Female | Male | Female |
| Benign nodules | I-131<br>Ext. X or Gamma | 14.6<br>75.6 | 33.7<br>174 | 61.6<br>318 | 147<br>729 |
| Cancers | I-131<br>Ext. X or Gamma | 8.23<br>24.7 | 18.5<br>55.6 | 31.5<br>94.6 | 71.5<br>214 |

*Total lifetime risk for excess thyroid cancers per $10^6$ persons per Rad. Approx 10% of excess cancers will be lethal

Source: NUREG/CR-6310

Fetal risk estimates are shown in Table 3. Limited data is available on in-utero exposure to radioiodine therefore the risk for delayed effects is considered comparable to a child and the reported risk estimates are taken from estimates for persons under 18 years of age at time of exposure.

Table 3. Lifetime risk estimates for fetal exposure *

| Exposure source | Thyroid effects | | | | |
|---|---|---|---|---|---|
| | Nodules | | Cancer | | Congenital Hypothyroidism |
| | Male | Female | Male | Female | |
| I-131 | 90 | 180 | 42 | 84 | 17 |
| Ext. X or Gamma | 465 | 930 | 126 | 252 | 83 |

*Per $10^6$ fetal thyroid rads and based on a 75 year lifespan

Source: NUREG/CR-6310

V. Potassium Iodide

Accumulation of radio-iodine by the thyroid may be blocked by use of potassium iodide. Potassium iodide works by diluting the proportion of radioactive iodine to stable iodine in the circulating system and by suppression of iodide transport across the thyroid membrane. Potassium iodide taken before exposure will reduce uptake by greater than 90%. Studies have shown blocking rates of 98%, 91%, 84% and 60% for administration 0, 1, 2, and 3 hours after an oral administration of radio-iodine[7]. Attachment 2 shows a calculated curve for blocking efficiency.

The adverse reaction incident rate for a daily oral dose of 130 milligram of potassium iodide is 1 in 10,000,000. This estimate is based on reported reactions to cough syrups and expectorants that contain potassium iodide. Few adverse reactions have been reported and none were life threatening. Potential adverse reactions are iodide induced hypo/hyper-thyroids, rash, iodema, swelling of salivary glands, rhinitis, and anaphylactic (hypersensitive) reactions[8].

Potassium iodide is manufactured in pill and liquid suspension form as an over the counter product. Local availability is questionable. Two area pharmacies were contacted. Both stated that it would need to be ordered and one stated that a prescription is required. Apparently, there is a common misconception that the Food and Drug

Administration authorized potassium iodide only for emergency response organizations and that private citizens must go through a physician if they wish to obtain it.

VI. Accident Analysis

12 isotopes of iodine are produced as result of fission. However, only 5 are produced in sufficient quantity to be of concern in the event of a release. Of these, iodine 131 contributes 60 to 70% of the thyroid dose, iodine 132-135 contribute 20 to 30% and the remainder, 10% or less, is from other radio-isotopes present in plume or ground level contamination[9]. Dose conversion factors are given in table 4.

Table 4 Thyroid Inhalation Dose Conversion Factors for Iodine Isotopes (Source NUREG/CR-6310)

| Isotope | Half Life | Dose Conversion Factors, Rad/uCi inhaled | | | |
|---|---|---|---|---|---|
| | | 0 -12 mos | 1-11 yrs | 12-18 yrs | >18 yrs |
| I-131 | 8.05 d | 12.99 | 7.26 | 2.78 | 0.88 |
| I-132 | 2.3 hr | 0.076 | 0.027 | 0.01 | 0.006 |
| I-133 | 20.8 hr | 2.63 | 0.84 | 0.36 | 0.16 |
| I-134 | 52.5 min | 0.011 | 0.005 | 0.002 | 0.002 |
| I-135 | 6.7 hr | 0.42 | 0.14 | 0.05 | 0.03 |

Various nuclear reactor accident consequent analyses exist, with widely varying results. The wide variation of outcomes is a result of the context of the study. For instance 'worse case' studies will provide the largest source terms and greatest offsite consequences, however these projected accidents scenarios have a very low probability for occurring, typically less than 1 in 1,000,000 per year. Models based on more likely scenarios have a slightly increased probability, but the offsite consequences are much reduced.

Tables 5 and 6 provide dose estimates taken from two sources. Table 5 summarizes selected data for a 'worse case' risk assessment for the Surry Nuclear Power Plant. The Surry plant is very close in design to the Maine Yankee plant. The worse case accident involves a loss-of-coolant accident, failure of emergency functions with subsequent melting of the core and total or partial containment failure. Worse case analyses serve several functions, the first being to place an upper bound on possible accidents and more importantly to help identify improvements in safety systems that will reduce offsite consequences and/or further reduce the probability of occurrence[10].

Table 5. Hypothetical Accident Analysis for Surry Power Plant*

| Model | Accident | Containment State | Probability Freq/yr | Time to Release (hr) | Release fraction | Source Term (MCi) | Thyroid Dose at 1 mile (rem) |
|---|---|---|---|---|---|---|---|
| RSUR1 | LOCA with vessel breach | Rupture | 2.9E-7 | 6 | 0.35 | 241 | 4E5 |
| RSUR2 | | Leak | 2.4E-6 | 12 | 0.06 | 41 | 2E5 |
| RSUR3 | | No Failure | 3.3E-5 | 6 | 3E-5 | 0.02 | 6E2 |
| RSUR4 | | Bypass | 1.6E-6 | 1 | 0.115 | 79 | 1.5E5 |

Source: NUREG/CR 6310
*Surry. 3 loop PWR, 2441 Mwt

Specific worse case analyses have been done for Maine Yankee as part of the Probabilistic Risk Assessment. The frequency (risk) and projected consequences are comparable for the Surry case given above. (Only summary data was available for the Maine Yankee PRA at the time of this writing. This allowed some comparison, but did not provide complete data on accident sequences).

An alternative accident model may be found in the Maine Yankee Final Safety Analysis Report. Each nuclear power plant must conduct analyses on certain accident scenarios. However, the plants are allowed to take credit for functioning safety systems, in particular containment remains intact with slight leakage, and core/reactor vessel damage is limited, significantly lowering the offsite consequences. Dose estimates for thyroid and whole body are given in Table 6 for a postulated loss-of-coolant accident (LOCA) and for a single steam generator tube rupture[11].

Table 6 Maine Yankee specific analysis for selected accident scenarios

| Accident Type | Source Term | Release Path | Conservative case | | Realistic Case | |
|---|---|---|---|---|---|---|
| | | | Thyroid | WB | Thyroid | WB |
| LOCA | 100 % NG<br>50 % I<br>1 % SFP | Containment leakage at 0.1% day | 151 Rem | 2.6 Rem | 1.0 Rem | 0.04 Rem |
| Steam Generator tube rupture | 19E-3 Ci I<br>1566 Ci NG | Condensor, through filters to plant stack | | | 3.4E-4 Rem | 8.5E-3 Rem |
| | 17.18 Ci I<br>17400 Ci NG | same | 1.8 Rem | 0.53 Rem | | |

Source: Maine Yankee atomic Power Co Final Safety Analysis Report

VII. Emergency Response to Nuclear Emergencies

The Maine Emergency Management Agency coordinates emergency planning and response for nuclear emergencies. Emergency plans provide for the timely warning of an emergency, an organized manner in which to protect the public and the most efficient use of state resources.

Two planning zones are established for nuclear reactors. The first, extends ten miles in all directions. Plans are in place to alert and safely evacuate the public to reception centers located outside of this 10 mile area.The second zone extends 50 miles in all directions. Beyond ten miles the major impact of a nuclear accident is projected to be contamination of food crops. The 50 mile zone is a defined area for planning for control of contaminated foodstuffs[12].

There are 4 defined emergency action levels for nuclear reactor emergencies. These levels are based on plant conditions and potential for offsite consequences. State and local response is based on the emergency action levels. Response ranges from notification of state officials at the lowest level, to evacuation of the general public at General Emergency. Emergency Action Levels and key responses are summarized in table 7.

Table 7. Summary of EAL and State response

| Emergency Action Level | Condition | Action |
|---|---|---|
| Unusual Event | Potential degradation of plant safety | Notification of state officials |
| Alert | Actual or Potential degradation of plant safety | Notification of state and local officials,<br>Notification of school districts<br>Manning of Emergency Operation Facilities |
| Site Area | Actual or likely major failure of plant safety systems | Public notification via PEAS*<br>Activate Reception Centers<br>Evacuate school children (if in session)<br>Establish evacuation routes |
| General Emergency | Events which present an actual or potential threat to the public | Public notification via PEAS<br>General Evacuation or sheltering |

Source: State of Maine Radiological Emergency Response Plan, Maine Yankee Atomic Power Station
* PEAS: Public Emergency Alerting System

Two protective actions, sheltering and evacuation, are available for the general public. Sheltering may be used if a limited or controlled release of radiation is expected, or if conditions exist that would make evacuation a greater risk, than remaining in place. Sheltering is effective for limiting dose for short term releases, less than 2 hours. However, the effectiveness is much less for long release times.

Evacuation is the preferred protective action for the general public. This follows federal guidance which states " . . . recent studies have shown that for other than containment venting, this type [short term or puff release]

of release is not predictable, and most of the release and accompanying dose for a long duration release can be avoided be evacuating early. In addition, studies have shown that except for very limited conditions, evacuation in a plume is still more effective in reducing health risks than prolonged sheltering near the plant."[13]

State plans for schools call for several possible actions, depending upon emergency classification and whether school is in session. School Superintendents are notified at the alert or higher classification. Recommendations may be to delay or cancel opening, early dismissal, or evacuation of the school to a reception center. These activities would occur at alert or site area emergency, prior to protective actions for the general population. Under these plans. children would remain with parents, or be evacuated from the area prior to any major release of radioactivity from the nuclear plant (Attachment 3).

Evacuation time estimates are available for the year-round and peak summer populations expected to be within the ten-miles. The ten mile planning zone encompasses two major beaches and many popular tourist destinations. Estimates are summarized below. Attachment 4 is the estimate for all locations within 10 miles.

Table 8 Evacuation Time Estimate Summary

| | Evacuation Time Hours (hrs) | | | |
|---|---|---|---|---|
| | Fair Weather | | Adverse Weather | |
| | Summer Weekday | Off-Season Weekday | Summer Weekday | Off-Season Weekday |
| Full EPZ | 5.8 | 4.2 | 6.4 | 5.7 |

VIII. Efficacy of Potassium Iodide versus Evacuation

Arguments against stockpiling of potassium iodide cite the diminished effectiveness of potassium iodide to block uptake if not taken before or immediately after exposure and would therefore not be effective, and that evacuation offers a greater dose savings. However, thyroid dose can be reduced or minimized even if potassium iodide is taken post exposure.

- Iodide, though rapidly taken in by ingestion or inhalation, follows a slower time course for uptake by the thyroid, reaching a maximum value at approx. 10 hours post exposure (section 2)

- Experimental evidence indicates blocking of greater than 50% at 3 hours post exposure. (section 5)

- Accident analyses indicate that radioactive release times and duration may not be predictable. Analyses show releases may vary from immediate to many hours after the initiating event. (NUREG/CR-6310)

- Evacuation time estimates range from 3 to 7 hours (Maine Radiological Emergency Response Plan)

Clearly, there is an overlap of effective blocking time, possible release times and evacuation times. A significant dose savings can be achieved through administration of potassium iodide, even as late as 3 hours post exposure.

IX. Other State Experience

Two states, Tennessee and Alabama stockpile potassium iodide for the general public. Tennessee began in 1981 with distribution to 3,022 homes. This was time and labor intensive. Replacement stocks were made available in 1984 for voluntary pick-up at local health centers with 1800 homes obtaining KI. Stocks were again replaced in 1992, with only 1,000 homes participating. In the event of an emergency, the remaining stockpile would be taken to reception centers for distribution[14].

Alabama maintains a stockpile at local health centers. The stockpile is taken to reception centers for distribution.

X. Federal Policy

The National Council and Radiation Protection and Measurement published Report No. 55, "Protection of the Thyroid gland in the Event of Releases of Radioiodine in 1977. The purpose of the report was to consider the feasibility of using thyroidal blocking agents as an additional measure for protection of the public. Concern over radioiodines was prompted by release of the Reactor Safety Study (WASH 1400) in 1975. That report showed that in certain accident scenarios large quantities of radioactive material, including radioiodine could be released from commercial nuclear power plants. NCRP 55 concluded that potassium iodide is an effective blocking agent, and that potassium iodide 'can and may be stocked at . . . . . locations where emergency medical services are usually available.

The Food and Drug Administration responded with a request for New Drug applications for a specific oral dosing form of potassium iodide, (43 FR 58790, Dec 15, 1978) and then recommendations for use, (47 FR 28158, June 29, 1982). FDA concluded that the risks [of adverse reaction] of short term use of low doses of potassium iodide are outweighed by the risks of radiation induced thyroid disease. The FDA recommended that potassium iodide be available if estimated doses to the thyroid would exceed 10 to 20 rads. FDA also provided dose recommendations of 130 milligrams/day for an adult and 65 milligrams/day for a child.

Federal policy for potassium iodide distribution was published by FEMA in 1985. (50 FR 30258, July 24, 1985, attachment 5). The policy was developed by the Federal Radiological Preparedness and Coordinating Committee. This policy advised that potassium iodide be provided for 'emergency workers and institutionalized individuals' but advised against stockpiling for the general public. Emergency workers are singled out for distribution as being more likely to be exposed, the number of individuals per site would be small, storage and distribution can be controlled and individuals who may be sensitive iodine can be screened. These same assumptions may be applied to institutionalized individuals.

The FEMA policy statement cited evacuation as a more prudent protective action for protecting the general public.. The reasons given were that potassium iodide protects only the thyroid gland and that distribution to individual members of the public was considered problematic for reasons of inventory control, availability, and use relative to other protective actions. However, the policy did state that potassium iodide "can be an effective ancillary protective action" and though cautioning against stockpiling for the general public, recognized that state and local authorities have the authority to protect the public health and may chose to distribute potassium iodide.

The Americal Thyroid Association requested that the FRPCC reconsider its position in a 1989 letter and in 1990 the NRC initiated a review of the potassium iodide use. The NRC review was prompted by new information about power plant accident source terms, revised thyroid risk coefficients, experience gained at Chernobyl and a recommendation by the American Thyroid Association that potassium iodide should be stockpiled for use during nuclear emergencies. The review was published as NUREG/CR-6310, An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident. (This was the primary reference for this paper). The NRC is considering the report and changes (if any) to their existing policy.

The Federal Radiological Preparedness and Coordinating Committee, FRPCC, met in June and again in October of 1996 to consider revising the 1985 federal policy. The FRPCC heard testimony from industry, government, professional scientific societies and the public. The FRPCC came forward with a recommendation that the existing federal policy should remain essentially unchanged, however, if a state or local agency chose to stockpile and distribute potassium iodide, the federal government, most likely, the NRC, would purchase the potassium iodide. To date, neither NRC or FEMA have taken any action on this recommendation.

XI. Chernobyl

The reactor accident at Chernobyl (Ukraine, 1986) resulted in the release of an estimated 45 million curies of radioiodine. The accident characteristics and meteorology caused significant dispersion and fall out over an extensive geographic area, including Ukraine, Belarus, Russia, and most of northern Europe. (Fission products were detectable in rain water locally). Potassium iodide was distributed to approx. 135,000 persons working in or residing near Chernobyl (within 30 kilometers of the reactor). Potassium iodide is assumed to have been effective in this group based on thyroid measurements from the treated population. However, a large population outside of this area received exposure to radioiodines ( and other fission products) and did not receive KI prophylaxis. Within this population there were 92,000 children with estimated thyroid dose of up to 200 rads. Risk estimates indicate



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an additional 300 thyroid cancers will occur in the Ukrainian population. Thyroid cancer has also increased in high fallout areas of Belarus and Russia. Thyroid cancer in Belarus has increased from 0.14 per 100,000 before the accident to 2.25 per 100,000 after the accident. Estimates for excess thyroid cancer in Russia are for an additional 349 cancers, an increase of 3 to 6 percent over the spontaneous rate[15].

Polish authorities distributed 10,500,000 doses potassium iodide to children and 7,000,000 doses to adults. The potassium iodide was in the form of a saturated solution. Distribution did not begin until two days after the first indications of radio-iodine contamination were found. The Polish authorities first detected radio-iodine in air samples collected on April 28th, the day after the accident began. High air concentrations continued to be measured so that the Polish authorities decided to distribute potassium iodide by late afternoon on the 29th. By this time, a large part of the population had received an exposure from airborne radioiodine. However, the Polish authorities recommended the potassium iodide to reduce further exposure from inhalation and ingestion. Generally, potassium iodide was considered to have provided significant dose reduction. Adverse reactions were minimal. A small percent ( < 1%) of newborns given a single dose experienced a transient raise in thyroid stimulating hormone and a decrease in $T_4$ (thyroxine), but returned to normal values within several weeks. Of adults, 5 % reported some side effect, with <1% having a medically significant effect, requiring follow-up or treatment[16].(attachment 6)

XII. Recommendations and Guidelines

The American thyroid Association supports stockpiling of potassium iodide. The ATA first published a review and recommendations for potassium iodide in 1984. At that time, the ATA did not recommend that a stockpile be developed, but did advise that planning for distribution should be considered. The ATA revised their recommendation in 1989 and advised that stockpiling of potassium iodide at central locations would be prudent. (Attachment 7)

The World Health Organization has issued guidelines for iodine prophylaxis for various groups. The WHO guidelines address pregnant women/lactating mothers, infants/children and adolescents and adults. The groupings reflect varying sensitivities and iodine-thyroid kinetics of the respective groups. The full guidance is given in attachment 8.

The Food and Drug published guidelines for use and recommended dosages. This is given in attachment 9.

XIII. Considerations for Distribution

Generally, distribution to the general public at individual homes is viewed as fraught with problems. The greatest being the uncertainty of potassium iodide being truly available to someone in their home. The experience of Tennessee seems to be that only a small percentage of the general population has an ongoing interest, and that availability of potassium iodide cannot be assumed for the population as a whole. A citizens group (Tennessee?) did suggest that a sealed container of potassium iodide be affixed to electric meters. This would allow periodic inventories and change out, without directly involving the homeowner, while placing potassium iodide near at hand. However, this was rejected due to questions regarding temperature stability, apartments with multiple collocated meters and damage or theft (remark during public comment period).

Distribution to schools is also problematic. Maintaining an inventory at a particular school is no different than a stockpile at any public facility and may be easily controlled. There were significant questions about actual distribution and liability, also that children are in school only 6 to 7 hours per day. There were several questions on distribution, one being who would actually administer the potassium iodide to the children. Would this be a teacher or a nurse, who would screen the children for allergies and would a teacher be willing to do this? There were several anecdotal remarks from parents of school age children and the requirements for permission slips for medications. The tenor of the discussion seemed to be that administration at schools would be difficult, would only be available less than half of the time to the student, would be unavailable to other members of the public and the students outside of school.

Liability was uncertain. The Maine Attorney Generals office had provided a brief opinion on immunity for the state, but were not asked about liability for local school districts. (An attorney was planning to be present for the Dec. 6 meeting to discuss liability, but was unable to attend) This was an unresolved question.

Generally, issuance of potassium iodide would seem to fall outside of the state's general immunity, but may be covered as a discretionary function by public health officials. Before discretionary use the state may consider circumstances for use of the product, any federal guidance, actions by other states and a risk-benefit analysis for the product. (attachment 9)

Several members of the public, state officials and utility representatives contributed to the discussion of this issue. Generally, remarks were questions on particular areas under discussion. However, several citizens directly encouraged the committee to recommend that potassium iodide be distributed for the general public and school children in particular. Mr. Peter Crane addressed the committee and provided written remarks. These are given in attachment 10.

Attachments

1. Figure 1 from Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide, March 1981, Dept. of Health and Human Services

2. Figure 2 from Reference 7

3. EPZ School Evacuation Logistics, Maine Emergency Management Agency

4. Evacuation Time Estimate Summary, Maine Emergency Management Plan

5. Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

6. Correspondence from Dr. S. Thomas Bigos and presentation notes from David Larrivee

7. Statement by the American Thyroid Association

8. Recommendations of the World Health Organization

9. Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency: Final reocmmendations on Use. U.S. Food and Drug Administration

10. Correspondence from Chris Leighton, Maine Attorney Generals Office

11. Statement from Peter Crane

References

1. NCRP 55, "Protection of the Thyroid gland in the Event of Releases of Radioiodine", National Council and Radiation Protection and Measurement (NCRP Report No. 55), 1977

2. FEMA, Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent, FR Vol. 50, No 142, 30258-30259, July 24, 1985

3. NUREG/CR-6310, An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident, 1995, U.S. Nuclear Regulatory Commission

4. Limits for Intakes of Radionuclides for Workers, ICRP Publication 30, 1979

5. NUREG/CR-6310

6. NUREG/CR-6310

7. Meck, R.A., Chen, M.S., Kenny, P. J. "Criteria for the Administration of KI for Thyroid Blocking of Radioiodine." Health Physics, V48, No 2, pp 141-157, 1985

8. NUREG/CR 6310

9. NCRP 55

10. NUREG-1150, Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants, 1990, U.S. Nuclear Regulatory Commission

11. Maine Yankee Final Safety Analysis Report, Chapter 14

12. State of Maine, Radiological Emergency Response Plan, Maine Yankee Atomic Power Station

13. NUREG-0654, FEMA-REP-1, Rev. 1, Supp. 3, Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants, July 1996

14. Federal Radiological Preparedness Coordinating Committee, transcript of public meeting, June 27, 1996

15. Chernobyl, Ten Years On, Radiological and Health Impact, November 1995, Nuclear Energy Agency, Organization for Economic and Community Development

16 Correspondence from Dr. S. Thomas Bigos, Director, Endocrinology Department, Maine Medical Center, including "Iodine Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks", May 1993, American Journal of Medicine

RJS/

Attach 1

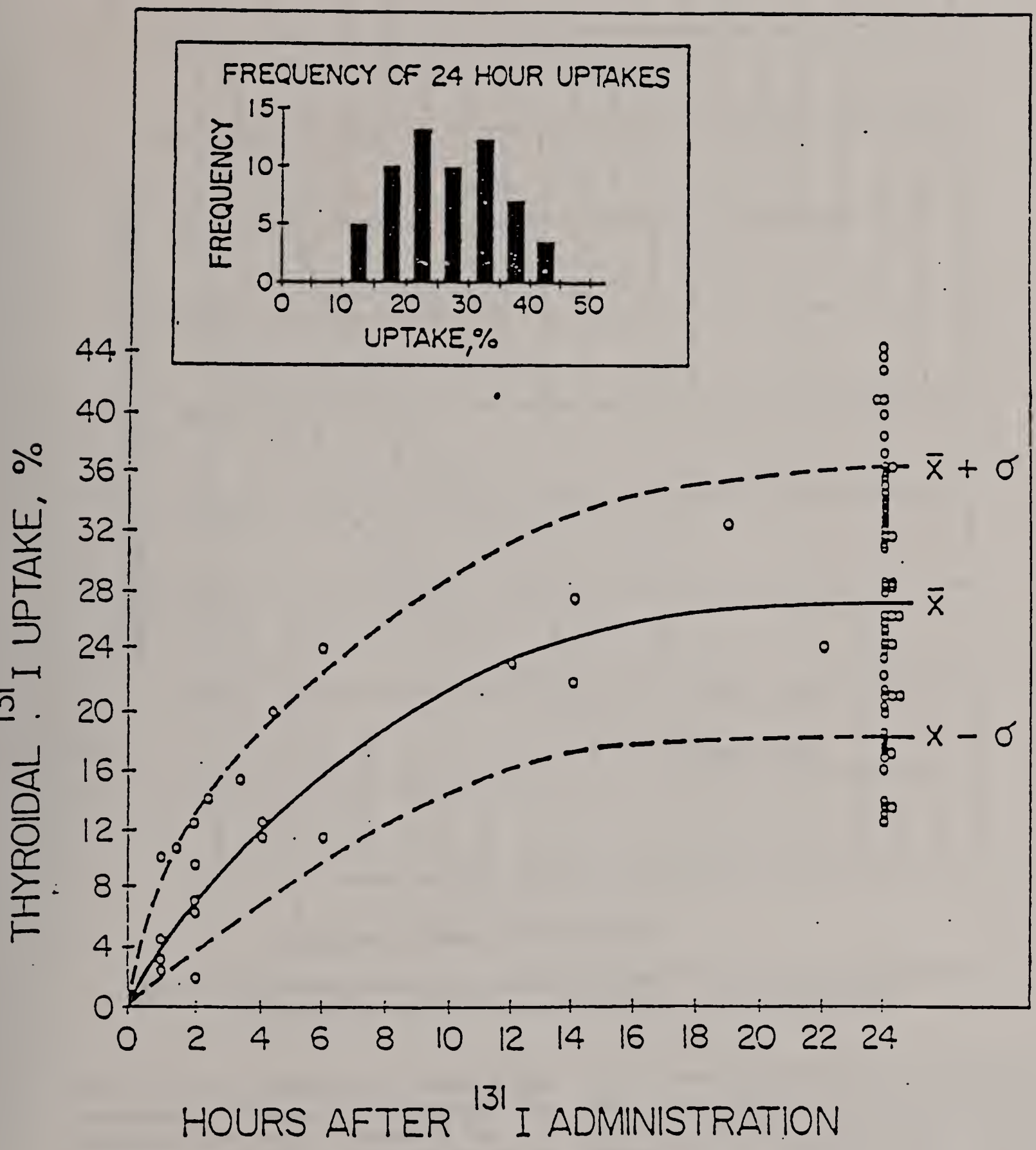


Figure 1. Thyroidal $^{131}I$ uptake in 62 euthyroid volunteers administered sodium iodide $^{131}I$ and their frequency distribution (from reference 10).

Attach 2



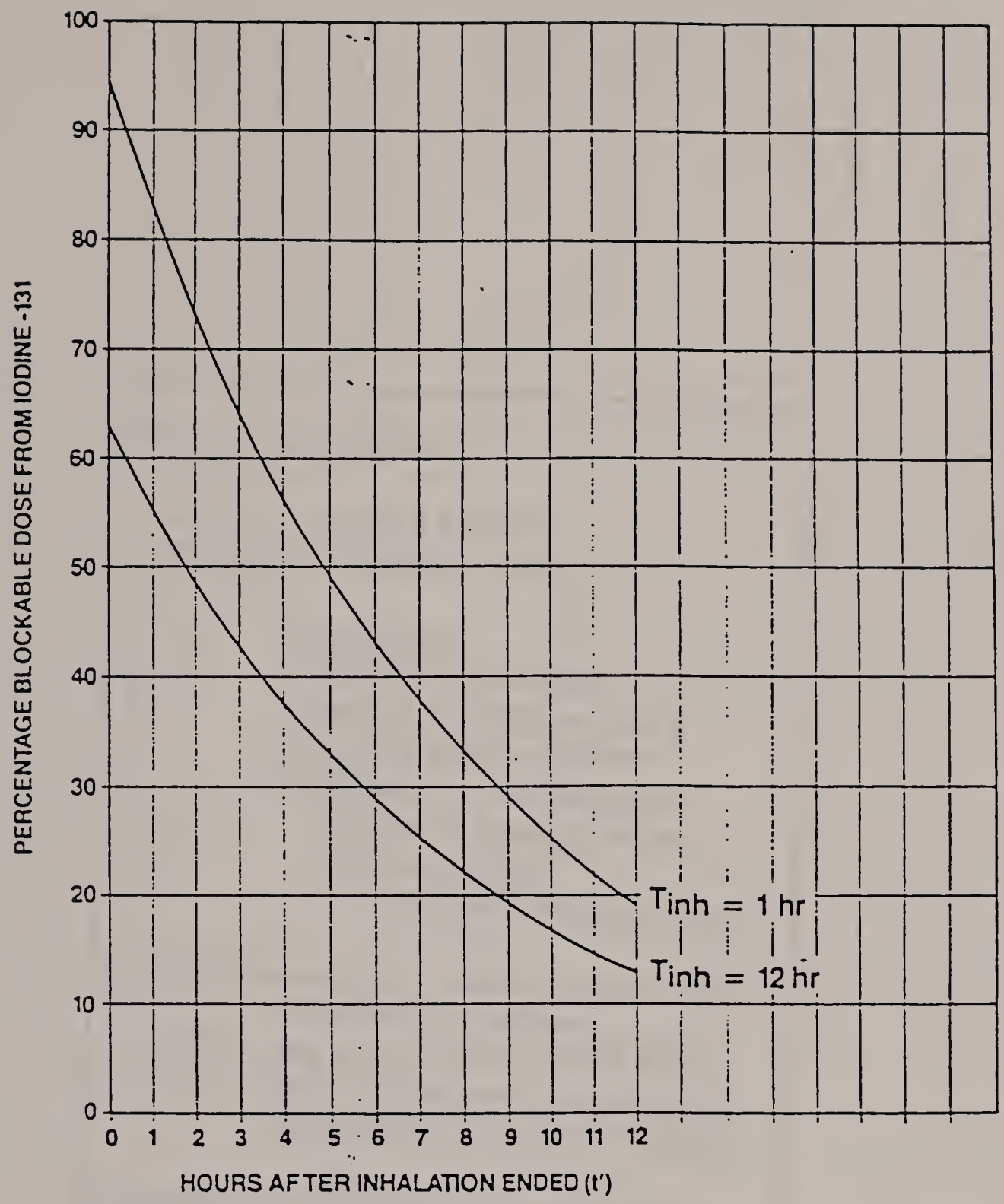


FIG. 2. The calculated percentage of blockable dose from $^{131}I$ as a function of elapsed time after inhalation ended for durations of inhalation, $t_{inh}$, of 1 hr and 12 hr.

estimation is a consequence of assuming that no excretion of I occurs during inhalation. The departure from constant slopes in Fig. 1 is interpreted to be due to extrapolations of the MIRD model beyond its originally intended use. In the case of the 1-hr inhalation, where the no excretion approximation is more accurate, it is noteworthy that the straight-line extrapolation intercepts the origin and closely approximates the normalized $MPC_a$. The assumption of no excretion leads to an overestimation of the blood-borne radioiodine at the

Attach 6

**KI Prophylaxis - Poland**

04/26/86 Chernobyl Incident
04/29/86 KI Prophlaxis begins :

Doses Given:
15 mG KI for Newborns
50 mG KI for children under 5
70 mG KI for other children
Prophylaxis recommended for
Pregnant & lactating women
but not required.
Not recommended for other adults.

10,500,000 doses given to children country-wide
( about 95% of children)
7,000,000 doses given to adults (about 23%)
6% of children and 2.6% of adults
self-administered tincture of iodine

Administered via droppers or automatic pipettes
(Saturated KI solution )

## Post - Exposure Study : Poland Children's Study Group (1989-90)

| | Prophylaxis | No Prophylaxis |
|---|---|---|
| # studied | 12,000 | 557 |
| Normal TSH | 91% | 93% |
| Low TSH | 5% | 4% |
| High TSH | 4% | 3% |

No significant difference between groups.

## Newborn Screening for Congenital Hypothyroidism - 1985, 1986, 1987

120-140,000 children screened per year
No change found in:

Transient elevation of TSH
Confirmed congenital hypothyroid
Serum T4 and T3 levels
Antithyroid antibody levels

* Therefore , no detectable long-term disturbance in thyroid function.

## KI Prophylaxis study - Adults with no previous thyroid disease (1989)

1,688 Men who received KI
3,363 Women who received KI
7,225 Men who did not receive KI
9,344 Women who did not receive KI

No difference in T4, T3, TSH or antithyroid antibodies.

## In adults with previous thyroid diseases, clinical outcomes were identical regardless of KI prophylaxis:

- no goiters became thyrotoxic
- no exacerbation of preexisting hyperthyroid
- no change in thyroid antibody titers
- no difference in Graves' disease prevalence.
- patients studied between 1986-1990

## Thyroid-related reactions seen in newborns on the 2nd day of life

3,214 newborns screened who had received KI
12 (0.37%) had decreased free T4 and increased TSH levels in serum.
The levels soon returned to normal.
No known sequelae observed to date (1993)
Note: the infants received 5 times the recommended mG KI/kG body weight dose that adults received.

## Children born in 1986 compared with children born in 1987

- examined in the 2nd & 3rd year of life
- no changes in thyroid status between groups

## 2 observed hospitalizations due to KI administration

- 18 million doses given total
- Both cases were adults with COPD and iodine sensitivity who took KI
- Both developed acute respiratory distress

## Extrathyroidal Effects of KI

| Symptom | Children | % | Adults | % |
|---|---|---|---|---|
| None | 11,482 | 95.4 | 4,833 | 95.5 |
| Iodine mumps | 0 | | 0 | |
| Parotitis | 0 | | 0 | |
| Headache | 22 | 0.18 | 35 | 0.69 |
| Stomachache | 43 | 0.36 | 32 | 0.63 |
| Diarrhea | 23 | 0.19 | 6 | 0.12 |
| Vomiting | 286 | 2.38 | 43 | 0.85 |
| SOB | 13 | 0.11 | 32 | 0.63 |
| Skin Rash | 129 | 1.07 | 63 | 1.24 |
| Others | 42 | 0.35 | 10 | 0.2 |
| total | 12,040 | | 5,061 | |

Note: no negative controls (Placebos) available for this study. The effect of KI on these symptoms vs. the "panic" effect cannot be differentiated.

# Countries Stockpiling KI

## Programs Briefly Described:

- U.K.
- Sweden
- German
- Switzerland
- Finland
- France

## Others:

- Austria
- Armenia
- Belarus
- Canada
- Czech Republic
- Japan
- Norway
- Poland
- Russia

NUREG-1633

# Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents

## Draft Report for Comment

Manuscript Completed: March 1998
Date Published: July 1998

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U.S. Nuclear Regulatory Commission
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301
415 6409

NOTE:
NUREG-1633
WITHDRAWN

correct others stockpile
Norway, Austria, Czech Rep, Slovakia, in, Russia
Belarus, Ukraine, Armenia, APPENDIX 1
Canada etc

## INTERNATIONAL PRACTICE ON THE USE OF IODINE PROPHYLAXIS

U.S. police exception not rule

### United Kingdom (UK) (33)

Offsite emergency plans for dealing with incidents involving the release of radioactive iodine should include procedures for distributing KI tablets. These plans are to be developed by the local health authorities on a site-specific basis. The requirements (34) state the following major points:

- Detailed plans should be drawn up for the rapid distribution of KI tablets to people residing within the detailed emergency planning zone (DEPZ) (1 to 3.5 km for NPPs (26)) or its equivalent.

- The aim ***must*** be to rapidly distribute the tablets distributed since the effectiveness of stable iodine for thyroid blocking depends on administration shortly before or as soon as possible after exposure to radioiodine.

- Local emergency planners will need to collectively discuss the best means of distributing KI tablets, including predistribution where appropriate, bearing in mind local circumstances and possible accident scenarios pertaining to their respective areas. The details of these arrangements need to be agreed upon within the framework locally established for planning the response to radiological incidents involving the release of radioactive iodine, since decisions will critically depend on the local geography, demography, and available manpower. The agreed-upon arrangements should be capable of immediate activation.

- Two recipients might be considered for predistribution:

  — less accessible households or communities

  — evacuation reception centers, police stations, hospitals, pharmacies, schools, and other strategic locations (so as to minimize delays in administration)

  Predistribution of KI tablets to less accessible households or communities may be undertaken, provided that the DPH has explicitly agreed to this policy.

- Site operators and consignors of mobile sources of radioactive iodine are responsible for providing and maintaining the bulk stocks of KI tablets. At reception centers and locations under their own control, health authorities and local authorities should take responsibility for storing and distributing the tablets.

- Even in areas in which the prime planned countermeasure is evacuation coupled with KI tablets, plans should include procedures for distributing the tablets to a sheltering population if such a scenario is deemed plausible by the local offsite planning body.

- When tablets are issued, they must be accompanied by guidance covering indications, contraindications, and dosage.

- In the highly unlikely event that distribution of KI tablets might be indicated following an incident other than at a major nuclear site, or with effects extending beyond the DEPZ, plans should address (in outline) how this might be accomplished so that arrangements can be quickly developed if the need arises.

**Sweden (35)**

In 1982, the Swedish Parliament decided that stable iodine tablets should be predistributed to all households within the 12 to 15 km around the four Swedish NPP sites. Approximately 50,000 households have received 20 tablets containing 65 mg potassium iodine. The predistribution is repeated every 5 years through a mailing organized by the regional authorities. The mailing includes information regarding basic facts about radiation, the related risks, and what to do in case of an accident.

In addition to the predistributed tablets, there are two central storage sites, one in Malmö, close to the Barsebäck NPP, and one in Stockholm. These two storage sites contain about 350,000 packages of 10 tablets each to be used if needed as a complement to the predistributed tablets in the vicinity of an accident.

The Swedish Radiation Protection Institute (SSI) is funded by the government to purchase the tablets. However, the nuclear power industry ultimately funds this program.

**Germany (36)**

On the basis of the 1989 WHO recommendations, Germany decided to reduce the intervention level and adopt a new philosophy concerning thyroid blocking in response to NPP accidents. This new philosophy will be implemented in spring/summer 1998. According to this new philosophy, persons over 45 years of age should not take iodine tablets because the drug could cause a greater health risk than the radioactive iodine averted by KI.

In addition, the German philosophy states that KI tablets should be stored in a way that they can be easily distributed when needed. On the basis of accident analysis, government has proposed the following distribution strategy:

- Within a radius of 0 to 5 km of the plants, the tablets should be predistributed to households.

- Within a radius of 5 to 10 km of the plants, the tablets should be stored at locations allowing distribution within 2 to 4 hours (e.g., town halls, schools, hospitals, factories, etc.) or predistributed.

- Within a radius of 10 to 25 km of the plants, the tablets should be stored suitable buildings, and predistributed only in exceptional cases.

For areas beyond 25 km, iodine tablets will be stored at one or two central places for children up to 12 years of age and pregnant women. Storage will be in such a way that the tablets can be distributed within 12 hours after the decision is made. In addition, every inhabitant can purchase iodine tablets in pharmacies without a prescription.

Packages distributed to homes will contain 10 tablets of 130 mg KI. Packages will have a clearly readable inscription and an instruction leaflet containing understandable information concerning thyroid blocking, as well as a warning concerning misuse and overdose.

Plant operators and/or the energy industry may be required to pay for the tablets, but this is still under discussion.

**Switzerland (37)**

Iodine prophylaxis tablets have been purchased for the entire population in Switzerland (i.e., 10 tablets for each person, totaling 70 million tablets in all). The tablets are distributed as follows in the area surrounding the NPPs:

- Within EPZ 1 (about 5 km), the tablets are predistributed to households.

- Within EPZ 2 (about 20 km), the tablets are stored at the community offices, thereby allowing rapid distribution.

- The remainder of the tablets are stored at the state level.

In the event of an accident, the National Emergency Operation Center (NAZ) is responsible for making recommendations concerning protective actions. The plans call for the following provisions:

- At the Warning Level (similar to a U.S. Site Area Emergency), the communities activate their own KI distribution system.

- At the General Emergency Level (similar to a U.S. General Emergency), the people within zone 1 are advised to go to the shelter and to take a first dose of KI; the people in zone 2 are advised to go to the community distribution center, where they will obtain the tablets and shelter.

It is important to note that there are special "fallout" shelters for virtually everyone in Switzerland,

**Finland (7)**

In the event of a severe reactor accident, the basic protective actions in Finland are as follows:

- Preventive evacuation within 5 km (before the release)

- Elsewhere in Finland, sheltering (preferably inside one's own home) and with iodine taken as prophylaxis.

In principle, every person has iodine tablets available. In 1993, the Ministry of the Interior decided that all workplaces with 25 employees or more, schools, and similar organizations should have a reserve of iodine tablets (2 per person). In addition, block houses having 4 or more flats should have KI tablets available for all residents.

Within 5 km of a NPP, the plant has to predistribute iodine tablets to persons staying in all permanent and vacation houses (independent of the number of households), as well as to all workplaces.

People living in single family houses outside the 5-km zone must buy tablets from pharmacies (freely sold and inexpensive). Many cities provide the tablets to all of their citizens without any cost.

In addition, all towns and municipalities have central storage locations for iodine tablets, and each is responsible for reserving tablets for 25 percent of the population staying in the area. Visitors and tourists will obtain their tablets from these central storage locations.

Instructions on the use of KI and dosage are provided with the tablets. Instructions were also mailed out in 1993, and are provided in telephone books.

**France (39)**

France has decided to follow the Swiss model for the use of KI. The Prime Minister issued the following instructions in April 1997:

- Within the 5-km zone surrounding a NPP (or more depending on the local demographic and other conditions), iodine prophylaxis tablets will be predistributed to families. In addition, stocks will be available at schools, day-nurseries, hospitals, and other public buildings. The total number of affected persons is about 600,000.

- Within the 5 to 10 km zone, stocks will be available for the local population. Tablets will not be predistributed but the local people can obtain the tablets in advance.

- Within France, there are stocks (mainly in hospitals) of about 4 million additional tablets.

In addition, anyone can get stable iodine tablets free of charge from a pharmacy without a prescription (this is new).

JOHN KERRY
MASSACHUSETTS

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
COMMERCE, SCIENCE, AND TRANSPORTATION
FOREIGN RELATIONS
INTELLIGENCE
SMALL BUSINESS

# United States Senate

WASHINGTON, DC 20510–2102

September 29, 1999

Ms. Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Ms. Vietti-Cook:

I am writing on behalf of the state-wide Massachusetts Coalition to Stockpile KI (Potassium Iodide). They have written a petition and collected a number of signatures regarding the U.S. Nuclear Regulatory Commission's Proposed Rulemaking (PRM-50-63A), Consideration of Potassium Iodide in Emergency Plans.

After reviewing the scientific evidence, the benefits of potassium iodide (KI)' appear to justify the expense. Since nuclear accidents are unforeseeable, our only protection is unabridged preparation. We must learn from the tragedies of the past, such as Chernobyl and Three Mile Island, in order to prevent them from occurring in the future. We cannot guarantee that there will never be another Chernobyl, but we can take every possible precaution known to us to contain the devastating effects of such a disaster.

KI must be administered either prior to exposure or up to six hours after exposure in order to be effective. Due to the time-sensitive success rates of KI, it should be stockpiled in every shelter, school, reception center, and hospital within the effluent pathway defined as the Emergency Planning Zone. It must also be available for purchase in pharmacies that are within the near field. State stockpiles would be appropriate for the far field, and could be located in the Emergency Planning Agency's Headquarters and sub-stations.

The question remains of who should provide the funding for the stockpiling of KI, replenishment, and associated distribution and public education costs. Perhaps, this responsibility should be borne by the individual plants as part of their responsibility for emergency preparation.

I ask that you reconsider the petition submitted by Mr. Crane on behalf of the Massachusetts Coalition to support the use of KI as an emergency planning requirement. The NRC is in a position to prevent a future disaster from claiming additional lives. Please rise to the occasion and make KI a requirement.

email: john_kerry@kerry.senate.gov
www: http://www.senate.gov/~kerry/

PRINTED ON RECYCLED PAPER

# News from Ed Markey

United States Congress | Massachusetts Seventh District

**FOR IMMEDIATE RELEASE**
**October 1, 1999**

**Contact: David Moulton**
**(202) 225-2836**

## JAPAN FIGHTS RADIATION EXPOSURE WITH IODINE— US NUCLEAR AGENCY REFUSES TO STOCKPILE IT

**WASHINGTON, DC**— In Tokaimura, Japan authorities distributed iodine tablets in order to prevent health effects from the nuclear criticality accident there. According to a U.S. State Department official, police distributed iodine tablets to residents who were told to stay in their homes in order to avoid contact with poisonous fallout from the accident. Potassium iodide tablets are used to prevent uptake into the thyroid of a radioactive isotope of iodine that is a byproduct of nuclear fission reactions, and thus prevent thyroid cancer and hyperthyroidism from ingesting the radioactive iodine. In Japan iodine tablets are stockpiled at local hospitals for this purpose.

In the U.S., however, stockpiling of potassium iodide has been stymied by the refusal of the Nuclear Regulatory Commission (NRC) either to buy the tablets or to require nuclear power plants to do so. According to answers the NRC provided in response to questions from Rep. Edward J. Markey (D-MA) following a recent Congressional oversight hearing, the NRC has spent more than $2.6 million studying the issue over the last ten years when it would only cost $3.25 million to buy enough iodine for all states with nuclear reactors. The NRC recently asked states to consider storing iodine near plant sites but did not require them to do so.

Rep. Markey said, "Stockpiling iodine is a simple, cheap, and effective way to prepare for the terrible possibility of a nuclear accident. The refusal of the NRC to carry out this measure is outrageous and unconscionable. They dither and delay. Someday a radioactive cloud could spread over an American city as it has over Tokaimura, Japan, and we had better be ready. The NRC should just do it."

NRC and the Federal Emergency Management Agency (FEMA) have been locked in an internecine battle over the issue. In an April 29, 1999 letter to the NRC, FEMA Director James L. Witt said that the Commission's proposal would "complicate, not strengthen radiological emergency preparedness." Rep. Markey said "The tragic accident in Japan shows that we do not have time for bureaucratic games. The time to protect the public by stockpiling iodine tablets is now."

# # #

NRC PROPOSED RULE 1999
• CHERNOBLY
• CONTRAINDICATIONS
• WHO GUIDELINES
• TIMLINESS ADMINISTRATION



[Federal Register: June 14, 1999 (Volume 64, Number 113)]
[Proposed Rules]
[Page 31737-31749]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr14jn99-13]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG11

# Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

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SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing an amendment to its emergency planning regulations governing the domestic licensing of production and utilization facilities. The proposed rule would amend the current regulations to require that consideration shall be given to including potassium iodide (KI), as a protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant. The proposed rule responds to petitions for rulemaking submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

DATES: Submit comments by September 13, 1999. Comments received after this date will be considered if practical to do so, but only those comments received on or before this date can be assured of consideration.

ADDRESSES: Comments may be sent to the Secretary of the Commission, Attention: Rulemakings and Adjudications Staff, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or may be hand-delivered to One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. Copies of comments received may be examined at the Commission's Public Document Room at 2120 L Street NW (Lower Level), Washington, DC.

You may also provide comment via the NRC's interactive rulemaking web site on the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files in any format that the NRC web browser supports. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-6215; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-3224. Internet: MTJ1@NRC.GOV.

SUPPLEMENTARY INFORMATION: By undertaking this rulemaking, the Commission, while not adopting the exact language suggested by the petitioner, is proposing to grant a petition for rulemaking (PRM-50-63A) submitted by Mr. Peter Crane on November 11, 1997. That petition

of which 20 utilities, 9 State governmental agencies, 2 utility interest organizations, 1 letter signed by 12 health physicists, 2 State universities and 1 member of the public were against the granting of the petition for rulemaking. Those letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the revised petition in the Federal Register. In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register notice published on January 21, 1998 (63 FR 3052). A total of 82 comment letters were received, of which 13 utilities, 3 State governmental agencies, 1 utility interest association, and 1 member of the public were against granting the petition for rulemaking. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 1 from the petitioner), 3 physicians, 2 U.S. Senators, and 1 State Representative. The following issues were raised by the public commenters with an accompanying NRC staff response:

Issue 1: Nearly all nations with nuclear power protect their citizens by having KI readily available and the logistics of distribution do not seen to pose any significant problems. Would implementing a policy of using KI for the general public be so difficult?

Staff Response: At the November 5, 1997, Commission meeting, senior NRC

[[Page 31742]] CHERNOBYL — THYROID / KI

staff members told the Commission: ``We recognize that there are difficulties in distribution, but they are not insurmountable. If a decision is made by the State to do it [stockpile and/or predistribute KI] we can figure out a way to do it.'' It is the staff's perception that if the State decides to include KI as a supplemental protective measure for the general public, one possible method of implementation could be that the State could make KI readily available where other over-the-counter drugs can be purchased. The public could be informed of the drug's availability through the yearly emergency preparedness information brochure that is mailed out to all residents throughout the 10 mile EPZ. It would then be up to individual members of the public to obtain and store this supply of KI, which should then be available for use in the event of an emergency. The administration of the KI could be at the direction of the State Medical Officer.

Issue 2: It is ``factual that the 1986 Chernobyl accident clearly demonstrated the benefit of having KI readily available. In Poland, where authorities expediently administered 18 million doses of KI, 97 percent of all Polish children were protected from thyroid disease. In contrast, there are soaring rates of childhood thyroid cancer, 200 times pre-Chernobyl levels, in the former Soviet republics of Russia, Belarus, and the Ukraine because very little KI was administered, too long after exposure.''

Staff Response: The Chernobyl reactor (a RBMK-1000 design) is located in the Ukraine close to Belarus. The accident occurred at 01:23 on Saturday, 26 April 1986, when explosions destroyed the reactor core and reactor building. The explosions sent debris from the core flying into the air and exposed the reactor core to the atmosphere. The heavier debris from the plume was deposited close to the site. In general, the initial release is thought to have risen to over 1 km in altitude, thereby resulting in much lower doses close to the site than those expected from a ground level release. The major release lasted 10 days, during which most of the noble gases and more than 40 percent of the iodines are estimated to have been released. The varying meteorological conditions, release rates, and release heights resulted

in very complex dose and ground deposition patterns.

It is often assumed that ingestion was the major source of thyroid dose early in the accident. However, the contribution of inhalation cannot be assessed because air sampling was not effectively conducted early in the accident. As of 1996, except for thyroid cancer, there has been no confirmed increase in the rates of other cancers, including leukemia, among the first responders, liquidators,\2\ or the public, that have been attributed to release from the accident.

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\2\ Liquidators are a large number (about 200,000) of workers and military personnel who performed cleanup, construction of the sarcophagus, and other operations in the contaminated zones following the accident.

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Belarus Experience. With the Chernobyl plant located only 4 miles (7 km) away, Belarus was heavily impacted by the accident. This impact was heightened by the fact that protective actions were not implemented in Belarus during the first six days after the accident. Several authors have stated that KI was distributed to the population in Belarus during the first week following the accident.\3\ However, there is no confirmed published data on the dosage, coverage, or other details concerning the implementation of the thyroid blocking in Belarus.\4\ In addition, cows typically grazed in Belarus at the time of year when the accident occurred, and yet no efforts were taken to restrict the consumption of contaminated milk for the first 10 days following the accident.

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\3\ Personal communication, E. Buglova M.D., Head Laboratory of Radiation Hygiene and Risk Analysis, Ministry of Health, Republic of Belarus, December 1997.

\4\ ``Thyroid Cancer in Children Living Near Chernobyl, Expert Panel Report on the Consequences of the Chernobyl Accident''-- Williams D. et al., K.H. ECSL-EAEC, Report EUR 15248 EN, Brussels-Luxembourg, 1993, p. 108.

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On May 2 (day 7 following the accident) the decision was made to evacuate the areas of Belarus and Ukraine within 18 miles (30 km) of the plant (30 km zone). The evacuation was completed on May 5, 1986.

Since 1990, a rapid increase has been observed in the incidence in thyroid cancer among Belarus children who were 0 to 14 years old at the time of the accident. Before the accident, the rate of thyroid cancer among this cohort was about 0.4 per 100,000; by 1996, this rate had risen to 3.9 per 100,000.<SUP>5</SUP>,<SUP>6</SUP> This included approximately 3,000 children, 0 to 18 years old, that were evacuated from the 30-km zone within Belarus. Among this group, four thyroid cancer cases have been detected since the accident. All of these cases were registered after the end of the latent period for radiation-induced thyroid cancer. Taking into account the spontaneous rate of this disease in this age group and the number of evacuated persons, all of these cases are considered accident-induced.

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\5\ E. Buglova et al., ``Thyroid Cancer in Belarus After the Chernobyl Accident; Incidence, Prognosis, Risk Assessment.'' Low Doses of Ionizing Radiation: Biological Effects and Regulator Control, Spain, November 1997, Contributed Paper, pp. 280-284.

\6\ ''Thyroid Cancer Incidence Rate in the Republic of Belarus.'' Okeanov A. et al., Radiation and Risk Bulletin of National Radio-Epidemiological Registry, Obninsk., 1995, Issue 6,

pp. 236, 239.

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The total number of excess thyroid cancers in Belarus children is currently about 750, and is estimated to reach a maximum of more than 3500 over the lifetime of this cohort.3, 4, 6 The vast majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site.

The increase in the rate of thyroid cancers in Belarus is concentrated among those who were youngest at the time of the accident. Fortunately, these cancers respond favorably to early treatment; to date, two or three of the Belarus children diagnosed with thyroid cancer have died as a result of that disease.\6\

Poland Experience. Poland detected increased levels of airborne radioactive contamination on the night of April 27, 1986 (day 2). Although there was no official notification of the accident by the USSR, it was assumed, on the basis of Tass News Agency reports, that the increases were attributable to the accident at Chernobyl. On April 28 (day 3), the country formed a governmental commission to recommend protective actions. Among these actions, the commission recommended intervention levels for taking protective actions on the morning of April 29 (day 4).<SUP>7</SUP>

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\7\ The Implementation of Short-term Countermeasures After a Nuclear Accident, Proceeding of an NEA Workshop Stockholm,'' Sweden, 1-3 June 1994, OECD 1995.

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On April 29, Poland's Minister of Health gave orders to prepare and distribute KI to the 11 provinces most affected. KI was to be made available through hospitals, public health centers, schools, and kindergartens. The country used its mass media to announce the protective action and to appeal for volunteers to assist in the nationwide distribution.

The Commission then instituted the following additional protective measures: <SUP>8</SUP>

\8\ Manual on Public Health Actions in Radiation Emergencies, WHO, European Center of Environmental and Health, Rome Division, 1995.

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<bullet> Feeding of cows on pastures or with fresh fodder was banned countrywide until May 15, 1986.

<bullet> Fresh milk with radioactivity concentration above 1,000 Bq/L was banned for consumption by children and pregnant or lactating women.

<bullet> All children under the age of 4 were given powdered milk through numerous distribution centers.

<bullet> Children and pregnant or lactating women were advised to eat a minimum of fresh leafy vegetables (until May 16, 1986).

[[Page 31743]]

The distribution of KI was initiated on April 29 (day 4) and was virtually completed by May 2 (day 7). This included the distribution of KI to more than 90 percent of the children under the age of 16 and about a quarter of the adults. A total of 10.5 million doses of KI were given to children and 7 million doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases.

Because of diminishing air contamination, the KI prophylaxis was not repeated. In the second phase of the response, powdered milk was made available to all children less than 4 years of age. This program effectively started on May 3 (day 8).

It is estimated that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions in the 11 provinces treated.\7\ Had the Russian authorities given prompt warning, the 24- or 48-hour gain in time might have improved the effectiveness of their response.

There were no reported serious adverse reactions except for two adults with known iodide sensitivity. About 36,000 medically significant reactions were also reported (mostly nausea).<SUP>9</SUP> Because of the low iodine concentrations in Poland it is doubtful that epidemiological studies could detect excess cancers resulting from intake of radio iodine.\8\

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\9\ A ``medically significant'' reaction was one for which the person suffering the reaction consulted a physician more than once. Nauman and Wolff, ``Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks,'' The American Journal of Medicine, Vol. 94, May 1993, p. 530. About .2% of the population that received KI had ``medically significant'' adverse reactions to KI. Id. However, ``[i]t should be pointed out that control values for these side effects in a population not receiving KI are not available.'' Id. That is, it is not known what the incidence of such reactions would be in a population under similar stress, but not receiving KI, and thus it is not known to what extent these adverse reactions were the result of KI.

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WHO / INTERNAT PRACTICES

International Practices--During this assessment, the NRC staff examined the current policies and practices regarding the use of thyroid blocking during Nuclear Power Plant accidents for a number of countries. The NRC staff accomplished this task primarily through personal communication with colleagues in each country. In general, the countries either are following or intend to implement systems that are consistent with the guidance promulgated by the World Health Organization (WHO). Specifically, the WHO recommends predistribution of stable iodine close to the site and stockpiles further from the site. These stocks should be strategically stored at points such as schools, hospitals, pharmacies, fire stations, or police stations, thereby allowing prompt distribution. A further description of the WHO guidance is provided below, followed by a discussion of the guidance promulgated by IAEA and a comparison between U.S. and international practice.

World Health Organization (WHO) Guidance. The main points of the WHO Guidelines <SUP>10,</SUP> <SUP>11</SUP> regarding the use of stable iodine are as follows:

\10\ International Basic Safety Standards for Protection Against Ionizing Radiation and for Safety of Radiation Sources, Safety Series No. 115, IAEA, 1996.

\11\ ``Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accident,'' Tecdoc-953, IAEA, July 1997.

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<bullet> Near field: Stable iodine should be available for immediate distribution to all groups if the predicted thyroid dose is likely to exceed national reference levels. Close to nuclear installations iodine tablets should be stored or predistributed to facilitate prompt utilization.

<bullet> Far field: Stable iodine should be available for

distribution to pregnant women, neonates, infants, and children if the predicted dose is likely to exceed reference levels.

Conclusion from Polish Experience. In Poland (1) Small amounts of radioactive iodine were deposited as a result of the Chernobyl accident, (2) no protective actions were taken for the first 2 days of the accident, and (3) protective actions (except sheltering or evacuation) were taken after the first 2 days of the accident. Because of the low iodine concentrations in Poland and the protective actions implemented, Poland has not detected excess cancers resulting from intake of radio iodines.

Overall Chernobyl Conclusion. The World Health Organization, almost every industrial country in the world with nuclear power plants, and the American Thyroid Association, believe that the low iodine concentrations, the banning of the consumption of fresh milk and the distribution and administration of 90 million doses of KI contributed to the observed lack of increase of childhood thyroid cancers in Poland. Most industrial nations with nuclear power plants have decided to stockpile KI around nuclear power for use by the general public.

In contrast to the Chernobyl experience, in the event of an accident in the United States, our emergency planning calls for protective actions, sheltering, evacuation, and removal of contaminated food from consumption all of which significantly reduce the risk of exposure of the public to all radionuclides. Making KI available to the public for use during evacuation or especially sheltering could, under certain conditions, reduce the risk resulting from exposure to one important group of radionuclides, the radioiodines. That is why current NRC guidance discusses KI for plant personnel, emergency workers, and institutionalized persons unlikely to be evacuated promptly.

In this light the Commission agrees that the use of KI may be determined by State and local emergency response planners to be a supplementary protective measure.

Issue 3: ``Stockpiling or predistribution of potassium iodide (KI) as a protective action would not add any significant public health and safety benefit to the current level of protection provided by existing emergency plans for commercial nuclear power plants. Our emergency plans focus on evacuation as the key protective action to prevent exposure since it protects against exposure to all radionuclides, not just iodine. In addition, the potential for misadministration of KI is present when predistributed to the general public, and incidents of misadministration have been informally reported at industry meetings by states which predistributed KI to the public.'' FDA

Staff Response: The Commission agrees that it is the State's prerogative to decide to include stockpiling or predistribution of KI as a protective action for the general public. The FDA concluded that risks from short term use of relatively low doses of KI are out weighed by the radiologically induced thyroid nodules or cancers at a projected dose to the thyroid gland of 25 rem or greater. In so doing, the FDA approved KI as an over-the-counter drug. The American Thyroid Association fully endorses the use of KI and, as previously discussed, there were only 2 significant adverse reactions and 36,000 medically significant reactions (nausea) in 90 million doses of KI after the Chernobyl accident. The taking of KI should require precautions similar to those associated with any other over-the counter drug, and, of course, the packaging instructions should be followed.

Issue 4: ``Evacuation is more feasible and practicable. Stockpiling of KI has logistical problems which we feel renders this idea impracticable and unmanageable.''

Staff Response: The staff agrees that evacuation is usually ``feasible and practicable'' and is the most effective protective action. If the State decides to include KI as a supplemental protective measure for the general public, one possible method of implementation could be that the State could make KI readily available such as by

TIMLINESS ADMIN KI

making it available where other over-the-counter

[[Page 31744]]

drugs can be purchased. The public could be informed of the drug's availability through the yearly emergency preparedness information brochure that is mailed out to all residents throughout the 10 mile EPZ. Individual members of the public would be responsible for obtaining and storing this supply of KI, which could then be available for use in the event of an emergency. Another approach to predistribution is to include stockpiling at reception centers for distribution during an evacuation. Other countries have found ways to effectively distribute KI when needed and the distribution issue is certainly not unsurmountable. The administration of the KI should be at the direction of the State Medical Officer.

Issue 5: The Three Mile Island experience has shown us that it is not easy to obtain an adequate supply of KI in an emergency.

Staff Response: The commenter is correct, in that it was difficult to obtain KI after the Three Mile Island accident. That is one reason why the Commission believes that planners should consider stockpiling KI, and why the Commission supports Federal stockpiles, so that States that have chosen not to stockpile KI could have access, albeit ad hoc and delayed, to an adequate supply in a radiological emergency at a nuclear power plant. As noted elsewhere in this notice, the Commission will work with other agencies to assure that there are Federal regional stockpiles that contain adequate supplies of KI. Moreover, the general availability of KI is greater now than at the time of the TMI accident, partly because of the FDA's approval of KI as an over the counter drug. Some States have elected to incorporate KI into the emergency response plans and have obtained adequate supplies for this purpose. The Commission is not aware of any factors that would constrain the availability of KI for stockpiling purposes. The Commission believes that an adequate supply of KI could be obtained.

Issue 6: Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown that the exposure can continue for days. Is the institution of KI blockade at any time in this period beneficial?

Staff Response: The administration of KI is most effective if done before or immediately after (within 2 to 4 hours) a release. Nonetheless, during a chronic exposure of several days, the administration of KI any time during the exposure period may block some uptake of radioactive iodine. However, the benefit diminishes quickly over time and may be very small if administered late. If a release is expected to continue for several days, the NRC anticipates that the public would be evacuated or other protective action would be taken, depending on the level of release. KI could nevertheless serve as a useful supplemental and complement to these primary protective actions.

Issue 7: KI is an effective thyroid blocking agent only when administered immediately before or after an exposure to radioactive iodine (that is, within one to two hours). Distribution of KI in a timely fashion to the general public following an accident could further complicate and decrease the effectiveness of implementing evacuation or residential sheltering.

Staff Response: The staff disagrees with this position. If a State chooses to include KI as an additional protective measure, it is anticipated that the State could make KI readily available to the public where other over-the-counter medicines are available or by other distribution means and that the public be made aware of its (the KI) availability, not at the time of an emergency, but KI could be made available year round.

Issue 8: One of the major impediments to distribution of KI to school children is coordination and administration of the program, e.g., the actual decision making process to administer KI or evacuate,

School

parental approval and recordkeeping, identification and documenting allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide.

Staff Response: The staff disagrees. Upon declaration of a general emergency there should be NO decision ``to administer KI or evacuate.'' The preferred protective action for the close-in population should be evacuation. The administration of KI should be treated in the same fashion as any other over-the-counter medication that might be given to children while away from home, after observing the instructions provided with the KI packaging. Prior parental approval to administer KI in the event of an emergency can and should be addressed in the planning process for any State that decides to use KI. The individual State may provide the appropriate guidance and establish a system for obtaining parental approval before the taking of other protective actions that are currently being followed in the EPZ around nuclear power plants.

Issue 9: Does the post-Chernobyl Polish experience show that large-scale deployment of KI is safe?

contra-indic.

Staff Response: Approximately 18 million doses of KI were distributed primarily, but not exclusively, to children. The bulk of the distribution took about three days. There were no reported serious adverse reactions except for two adults with known iodide sensitivity. The rate of serious side effects (10<SUP>-7</SUP>) is consistent with the frequency seen during routine use of KI for medical treatment of respiratory disease. The incidence of medically significant, but not serious, reactions to this single dose of KI was also very low (0.2 percent). In addition, no detectable long-term disturbance in children's thyroid function was detected as of 1989. Additionally, the FDA has approved KI for over-the-counter distribution. The staff, therefore, agrees that the post-Chernobyl experience has shown that large-scale deployment of KI is relatively safe.

Issue 10: Several comments raised the question of liability: ``Is the NRC prepared to address the number of legal implications should a member of the general public be given KI at their directive or recommendation and the individual have an extreme allergic reaction, possibly death?''; ``The Federal Register Notice does not address legal issues for states who decide to adopt KI and states who do not decide to adopt or administer KI to the public.''; ``The issue of legal liability should not be dismissed lightly. If the NRC decides to require stockpiling of KI for the general public, has NRC considered what liability may arise from any adverse health effects? No initiative such as this should be undertaken without resolution of this issue.''; ``Who would assume liability if the KI was used prior to the Governor ordering its use?'

Staff Response: The comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. To the extent that commenters are raising the potential for federal government liability for the promulgation of this proposed rule, the NRC believes that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require state and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the ``discretionary function'' exception to the Federal Tort Claims Act, 28 USC

[[Page 31745]]

2671, et seq.,<SUP>12</SUP> which protects the Federal Government from liability. The question of whether a State or locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular

# Federal Emergency Management Agency

Washington, D.C. 20472

APR 29 1999

Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Madam Chairman and Commissioners:

I read in the April 24, 1999 New York Times and in your press release that you voted to withdraw your commitment to fund the purchase of potassium iodide for States that elect to stockpile it for use by the general public in the event of a radiological release from a nuclear power plant. In addition to deciding that the NRC would not pay for State stockpiles, you announced that FEMA should pay for both regional and state stockpiles. I strongly oppose this unilateral decision that reverses your previous position and adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). The policy provides that if a State chooses to add potassium iodide as a supplement to its evacuation and sheltering protective actions, the State will inform FEMA and we will forward that request to the NRC to support the purchase.

Your abrupt retreat from repeated promises to the Federal community, states and the public is apparently based on a misapprehension of FEMA's authorizing legislation and a disregard of our view—and that of other FRPCC agencies—that regional potassium iodide stockpiles will not enhance local radiological emergency preparedness. On funding, we stand fast on our position that FEMA lacks authority and appropriations for acquisition of potassium iodide and thus, cannot and will not assume the NRC financial commitment to the States.

Based on concerns expressed by States, FEMA has always opposed the notion that Federal regional stockpiles of potassium iodide would be effective in the event of a release from a nuclear power plant. The complex logistics of storage and distribution far outweigh the usefulness of such a stockpile. Regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness.

NRC and FEMA must work together with the States to implement the FRPCC policy. As you may recall, this proposed policy would leave the option to the State on whether it would use potassium iodide as a supplemental protective measure for the general public. If a State opted to incorporate its use as a protective measure for the general public, and the NRC fulfills its commitment, funds will be provided for such a purchase.

In light of the significance of this issue, and the concerns being raised by the States, I would appreciate a response to this letter by May 28, 1999.

Sincerely,

James Lee Witt
Director

Attachments: NRC Potassium Iodide Funding Commitments
Federal Radiological Preparedness Coordinating Committee proposed policy and scheme for potassium iodide request & funding

cc: William Travers, EDO
FRPCC Agencies

Federal Emergency Management Agency
Washington, D.C. 20472

April 9, 1998

Mr. John C. Hoyle, Secretary
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Hoyle:

It has come to my attention that there may be some confusion regarding the Federal Emergency Management Agency's (FEMA) and the Federal Radiological Preparedness Coordinating Committee's (FRPCC) positions and proposed policy on the issue regarding the use of potassium iodide (KI) by the general public in the event of a radiological emergency at a commercial nuclear power plant. I am writing this letter to clear up any misunderstanding or confusion regarding the FEMA and FRPCC positions on this issue.

First, on page 7 of the Nuclear Regulatory Commission's (NRC) SECY-97-124, dated June 16, 1997, the NRC staff presented five reasons that, purportedly, the second FRPCC Ad Hoc Subcommittee on Potassium Iodide used as a basis to develop its recommendations for the plenary FRPCC. These reasons included reference by the NRC staff to the September 15, 1994, Subcommittee report and the following statement: "a lack of support for such an initiative by the states and the primary Federal regulatory agency (FEMA)." As you are aware, FEMA is not a regulatory agency, nor has FEMA taken a position of supporting or not supporting the use of KI by the general public in a radiological emergency. This statement was meant to refer to the lack of the NRC staff's support, not FEMA's lack of support. This matter was addressed at the November 5, 1997, public meeting with the NRC Commissioners, and the NRC staff did acknowledge that they were in error in making that statement. As indicated by Mr. O. Megs Hepler, III, Chairman of the FRPCC, during the November 5, 1997, public meeting, FEMA supports the current proposed FRPCC revised policy that states "the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective supplemental or ancillary protective action during a nuclear power plant accident."

Secondly, I want to address a comment from the Nuclear Energy Institute (NEI) in their response to the amended Petition for Rulemaking. NEI states that the FRPCC Subcommittee "reaffirmed its position of not advocating widespread stockpiling and distribution of KI for the general public." I am concerned that this statement could be misleading. Although the FRPCC Subcommittee did not affirmatively recommend widespread stockpiling, and, in fact, left the decision-making authority on use of KI by the general public with the State, and in some cases, local governments, the FRPCC Subcommittee did propose as part of the policy that if any State chooses to incorporate the use of KI as a protective measure for the general public then the Federal government would provide the funding for the purchase of such a supply. The plenary FRPCC unanimously approved this revised Federal policy.

A third statement I want to comment on was made by the Illinois Department of Nuclear Safety

(IDNS). IDNS was quoted, in an April 3, 1997, Commonwealth Edison Press Release, that "it is expected that a certain percentage of the public would have a negative allergic reaction to potassium iodide" and that a "joint federal task force" (presumably the FRPCC) agreed with that statement. Although that statement, on the surface, is not incorrect, it is somewhat misleading. The position of the FRPCC on the use of the drug is that it is safe and effective. The Food and Drug Administration (FDA) approved KI as a prophylaxis for the thyroid (to prevent that organ from absorbing radioiodine) in the December 15, 1978 Federal Register, and, at that time, KI was approved for purchase as an over-the-counter drug. This FDA approval was empirically reinforced by the experience in Poland with KI, subsequent to the Chernobyl accident.

Finally, when the NRC noticed the amended Petition for Rulemaking in the December 17, 1997, Federal Register for comment, it also referenced a draft April 15, 1997, Federal Register Notice, "Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent." It should be made clear that this document is a revised version of an earlier FRPCC draft Federal Register Notice, and while it accurately reflects the Subcommittee's recommendations, which were adopted by the FRPCC, it will still need to be formally approved by FEMA and the FRPCC once the funding issue and the petition are addressed by the NRC.

Please include these clarifications as part of the official NRC docket and record.

Sincerely,

Kay
C.
Goss
Associate
Director
for
Preparedness,
Training
and
Exercises

FDA



Taken together, the comments received during the public comment period and the actions of national and foreign radiation protection groups make these recommendations prudent because, although slightly above the range presented in draft recommendations (10 to 20 rem), a 25-rem projected dose to the thyroid is equal numerically to the Environmental Protection Agency's (EPA) upper Protective Action Guidance level for the general public and the United Kingdom's National Radiation Protection Board's upper level proposed for potassium iodide use. (EPA Protective Action Guides call for sheltering, evacuation, and controlled access as protective actions when the total accumulated thyroid doses are projected at 5 to 25 rem for the general population. The EPA guides do not specifically note the use of potassium iodide as a protective action for the general population.) These agencies would expect some protective action to be taken at 25 rem projected dose to the thyroid. Use of a single recommended value also eliminates questioned by State and local public health agencies about whether to use the upper or the lower part of a range of values.

FDA further recommends that officials responsible for radiation emergency response planning include in the emergency response planning a system of public information on the use of potassium iodide and a system of medical contact, reporting, and assistance.

Each State is responsible for formulating guidance on when, if at all, the public should be supplied with potassium iodide along with instructions on how to use it. In preparing guidance and making rules, State and local agencies should inform citizens of the nature of the radiation hazard and of the potential benefits and adverse effects of potassium iodide.

These final recommendations on potassium iodide use must be seen in the context of radiation emergency planning as a whole. The use of potassium iodide in the radiation emergency is not a panacea. It does not reduce the uptake by the body of other radioactive materials or provide protection against external radiation. The cost and effectiveness of other protective measures such as seeking shelter, evacuation, or respiratory protection also need to be considered.

Although FDA received written comments on the draft recommendations and considered them in formulation of these final recommendations, under 21 CFR 10.90 interested persons may submit further written comments on these final recommendations to the Dockets Management Branch (address above).

Dated: June 22, 1982.

Arthur Hull Hayes, Jr.,

*Commissioner of Food and Drugs.*

[FR Doc. 82-17468 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

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[Docket No. 82F-0181]

## Union Carbide Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for specification changes in polysulfone resins as articles or components of articles intended for repeated use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Julia L. Ho, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3629) has been filed by Union Carbide Corp., River Road, Bound Brook, NJ 08805, proposing that Part 177 (21 CFR Part 177) of the food additive regulations be amended to provide for a change in the molecular weight specifications and testing requirements for polysulfone resins as articles or components of articles intended for repeated use in contact with food.

The agency has carefully considered the potential environmental effects of this proposed action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 18, 1982

Sanford A. Miller,

*Director, Bureau of Foods.*

[FR Doc. 82-17471 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

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## National Institutes of Health

## Cancer Center Support Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Cancer Center Support Review Committee, National Cancer Institute, July 15-16, 1982, Building 31C, Conference Room 6, National Institute of Health, Bethesda, Maryland 20205. This meeting will be open to the public on July 15 from 8:30 a.m. to 10:00 a.m. to review administrative details, and to present reports by the Division Director and the Branch Chief. Attendance by the public will be limited to space available.

In accordance with provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on July 15, from 10:00 a.m. to adjournment, and on July 16, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. Robert L. Manning, Executive Secretary, Cancer Center Support Review Committee, National Cancer Institute, Westwood Building, Room 803 National Institutes of Health, Bethesda, Maryland 20205 (301/496-7721) will furnish substantive program information.

Dated: June 17, 1982.

Betty J. Beveridge,

*Committee Management Officer, National Institutes of Health.*

(Catalog of Federal Domestic Assistance Number 13.397, project grants in cancer center support, National Institutes of Health)

(NIH programs are not covered by OMB Circular A-95 because they fit the description of "programs not considered appropriate" in section 8(b) (4) and (5) of the Circular)

[FR Doc. 82-17464 Filed 6-28-82; 8:45 am]

BILLING CODE 4140-01-M

HEALTH

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
***

POTASSIUM IODIDE (KI) CORE GROUP MEETING
AmeriSuites Hotel
1520 West Baseline Road
Tempe, Arizona
Thursday, March 4, 1999

The above-entitled meeting commenced, pursuant to notice, at 8:30 a.m.

PARTICIPANTS:
ABY MOHSENI, CHAIRMAN
ED WILDS
JEAN TEMECK
BILL MCNUTT
MARCIA CARPENTIER
JIM HAREDMAN
ANDY SIMPSON
AUBREY GODWIN
JOELLE KEY
MIKE CASH
TONY SHERIDAN
MIKE NAWOJ
ANDREA PEPPER
MIKE JAMGOCHIAN

P R O C E E D I N G S
[8:30 a.m.]

CHAIRMAN MOHSENI: Okay. Today on the Agenda is going to be a member -- yes. We're on the record. We're on the record.

This is the day where we're going to discuss extensively the aspects, medical aspects of the medication KI. We will have a presentation by Dr. Tom Hamilton from Fred Hutchinson Cancer Institute in Seattle, on the Hanford Thyroid Disease Study that has come out in draft form late in January. That will be at 10:00 o'clock.

First, we're going to have the Draft WHO Guideline presentation by Aubrey Godwin. But prior to that we have the Agenda public comments. If there are any, we'd like to hear.

Anybody out there wanting to make any statements?

I'm also pleased to announce that we have Dr. Bob Seale, the Chairman of ACRS, here.

DR. SEALE: Not any more.

CHAIRMAN MOHSENI: Not any more?

DR. SEALE: We can only serve two years.

CHAIRMAN MOHSENI: So we're going to -- ultimately this document that we're going to produce will go through ACRS review and this will help provide a presentation on what the flavor of this document that will come out.

Also Dr. Jean Temeck is here with us today, obviously, for the FDA issues. And if there are no announcements, I think Aubrey Godwin has something for us.

MR. GODWIN: Yes. My wife and I would like to invite the members of the Committee out to our house for dinner tonight. I hope we have enough cars to get everybody there. I have some maps to show you how to get there, and those with cars we'll get together and make sure you have transportation. I can come back and pick some up but about 6:30 tonight. I invite you all.

CHAIRMAN MOHSENI: Great. And if we don't have any comments from anyone in the audience or any member here, then we can start with Aubrey's presentation.

MR. GODWIN: Let me say up front I do apologize for the cloudy weather. It's unusual. Sorry about that. I guess one day a week's not too bad, but just a little unusual.

Another thing I think you should to know is that I was not an author of this particular document. I attended a meeting and offered some comments. There were some people who had some quote, "experience" with emergency planning, and somehow I got chosen to be there. I'll try

Jean

Dr Temeck FDA KI Core group March 1999

A VOICE: 15 and under, thank you.

DR. TEMECK: And what, of course, we found as we all know,

was that there was a marked increased incidents in thyroid cancer in

children who were exposed to Chernobyl radiation. And the highest

thyroid cancer incidents occurred in those who were exposed from the

pre-natal period up to four years of age.

We do know that an increased incidents all thyroid cancer

was also reported in adults but the magnitude of the increase did not in

any way, shape or form approach the magnitude of the increase that was

observed in the children and we know that the marked increase in thyroid

cancer that occurred in the children was internationally corroborated.

However, we don't have any international corroboration on the increased

incidents that was observed in the adults.

And so it becomes clear that from this information that

children are certainly the most susceptible age group to radiation

induced thyroid cancer.

Temeck: Then next, there is a recent dose response estimate, this is

perhaps the most recent or certainly one of the most recent dose

response estimates that were made, published in the literature in Nature

March 5th of 1998 and by Jacob, et al, and in that paper what they show

is that there was excess thyroid cancer incidents observed in areas

where the mean iodine 131 dose to the thyroid in children was estimated

at only 5 rem. Now, this is a mean dose of iodine 131 to the thyroid.

MR. HARDEMAN: Were these areas close enough to the plant

/

that it's also reasonable to assume that they might also have been impacted by --

DR. TEMECK: By short-term --

MR. HARDEMAN: -- and by internal gamma?

DR. TEMECK: -- and gamma, yes.

MR. WILDS: What was the dose? Did they take into account the short-term iodine and the gamma to add on to see what the total dose to they thyroid was? You're saying mean for iodine 131.

DR. TEMECK: Right, that's what the paper was reporting was the mean iodine 131 dose to the thyroid.

MR. WILDS: Do we know the doses that came from shorter lived iodines?

DR. TEMECK: No, that we do not know. DR. TEMECK: That's right, to the thyroid. It was a combination of inhalation and ingestion. MR. NAWOJ: Do you know what the duration -- does the study address the duration of the exposures?

DR. TEMECK: No.

MR. NAWOJ: Whether it's a matter of hours or days or weeks?

DR. TEMECK: No. So this recent dose response analysis, as I say, was based on pooled data from the most effected countries which of course, as we know was the Ukraine, Belarus and the Russian Federation. DR. TEMECK: That's right, you could have gamma. Okay, and the purpose of this dose response analysis was to estimate the increased risk of developing thyroid cancer after exposure to radioiodine as a child or adolescent. The excess absolute risk was 2.3 for 10 to the 4 person year race and what they found was that this dose response relationship was layered and if you extrapolate that to one rem, there

is increased risk of thyroid cancer even at a one rem iodine 131 exposure to the thyroid. So this is an extrapolation back.

MR. WILDS: If you're not taking into account any of the gamma how can you say that it's just due to iodine 131?

DR. TEMECK: Because what they used -- to make this assessment of how much iodine 131 activity there was in the thyroid, they used estimates of what was the iodine 131 contamination in the soil and in the milk. They used a ratio of the cesium to the iodine 131 at different times during the accident, so they were trying to focus in on what was the contamination from the iodine 131.

MR. LANTZ: I've given Aby a report over there that shows hundreds of kilometers away there's still external doses of greater than nine rem.

CHAIRMAN MOHSENI: Jean, the document that is referenced there, this is the European Commission of International Atomic Agency World Health Organization that was put out in 1996. I'm sure you're familiar with it. It says, "Significant exposure to radioiodine extended more than 100 kilometers from Chernobyl and for the designated contaminated o-blast of the Ukraine, Gormel (ph), Bress (ph), Morg Eleven (ph), Belarus and Briance (ph), o-blast in the Russian Federation. Well over 3.5 million children were exposed. Within these areas there is a great variation in the estimated thyroid dose ranging from less that 100 milligray to over a tenth gray.

DR. TEMECK: Right. CHAIRMAN MOHSENI: And of course the exposure was not confined to those o-blasts only. The estimated mean dose for children in Mensch (ph) city over 400 kilometers from the Chernobyl plant was 60

milligray and an increased incidents in thyroid cancer has been recorded
in a population exposed as children to as little at 90 milligray of
external radiation". That's the nine RAD that was referred to here,
226.

It's important, I think, to insure that we have a consistent
baseline for the conclusions that are needed to be drawn. That's all.

At this stage, you know, we may want to better appreciate the baseline.

DR. TEMECK: I have it here. They specifically state in the
paper that there were 150,000 measurements of iodine 131 activity to the
thyroid, okay. And these were all measured using a collimated device.

In a re-evaluation of these measurements, referring to the ones I just
spoke about, we reconstructed average thyroid doses due to iodine 131
exposure for three regions close to Chernobyl and they mention these,
and for evacuees.

And then they go on to say here they took into account
contamination by cesium 137 of the ground and the settlement's location
to Chernobyl. In addition, they took into account data on milk and soil
contamination with iodine 131. So this is the background information
that they give with regard to this paper. And, what they're then
talking about what is the mean or average thyroid dose with regard to
iodine 131 that children received. And I'll pass around this paper so
that if you wish to look at it here, can do so. DR. TEMECK: I have not seen any data which specifically
gives support to how much was contributed by iodine 131 versus gamma.

This paper says -- they make a statement here that exposure to iodine
131 was responsible for most of the doses that effected the thyroids of
these children. R. TEMECK: I haven't seen though any papers that really
define precisely the contribution unless, Aby, you're aware of any data
that shows, you know, how much the iodine 131 contributed to the
increased incidents of thyroid cancer versus how much the contribution
was from gamma radiation. I haven't seen --
CHAIRMAN MOHSENI: We're looking -- yeah, I understand. And
I'm looking at basically the same documents that you have been looking
at and it's available and it's not conclusive, as you know.
DR. TEMECK: It's not conclusive, that is correct.
CHAIRMAN MOHSENI: Yes. R. TEMECK: No, it was not reported, that is correct. Any
other questions before I move on?
The increased incidents of thyroid cancer was observed out
to 250 miles from the accident's site and what was observed was that
there actually was a latent period of only four years before the
increase incidents of thyroid cancer was observed in children. So this
was a fairly short lag time.
Temeck: On the other hand, if you look at the incidents of thyroid
cancer in children who were born more than six months after the
accident, the incidents of thyroid cancer returns to pre-accident levels
and to those in unexposed countries. think you had a comment
to make? Okay. That iodine 131 was a major contributor to the dose in
these effected children is again, indirect evidence for this. One --

and I know we're going back to the same issue, the short lived isotopes
of radioiodine, 132, 133, 135, are felt to really -- their effect is
exerted close to the accident site. You would not expect to see a major
effect on the shorter lived radioisotopes.

And I mentioned the gamma radiation, that we did not really
see a marked increase in any of the other cancers that we saw for
thyroid cancer, but I know that you've made some comments about that,
Aby.

A VOICE: What would close mean?

DR. TEMECK: I can't give you a specific distance, I mean,
if that's what you're looking for.

A VOICE: Well, 250 miles was not close.

DR. TEMECK: That's right.

A VOICE: So would 50 miles be close or 10 miles or five
miles?

R. TEMECK: But no direct measurements were made of the shorter lived radioisotopes of iodine. Okay. Now, the Polish
experience, as we all know, they prophylaxed using single doses of KI.

They used a 15 milligram dose for newborns, actually a 50 milligram dose
for children who were less than five and then a 70 milligram dose,
single dose for all others.

And what was of most concern was the fact that in 12 of over
3,000 newborns who received single doses of potassium iodide on the
second day of life, they did develop a transient thyroid blockade.

There was a transient biochemical hypo-thyroidism which occurred in 12
of these newborns. And when the thyroid functions were repeated two
weeks later, the thyroid function was normal in all of those newborns.

So it certainly did not last longer than a two-week time frame. So I really don't feel -- and this is the feeling of the agency at this point, we'll look into this more, this issue, but this transient biochemical hypo-thyroidism that lasted at most two weeks, we do not have any data from the literature to suggest that this is a clinical problem.

**Temeck's evaluation Hanford Study**

Doctor Hamilton, as you know, gave a very excellent presentation, a very thorough presentation, on Hanford, so I'm going to just touch on some very basic points in this presentation. As we all know the Hanford Thyroid Disease Study was mandated by Congress in 1988 and the purpose of it was to evaluate the effects on the thyroid of radioactive iodine release from this nuclear site and it was specifically looking at the years 1944 to 1957.

It actualler in the in area residents was not increased compared to the 248 participants who had moved out of the region before the nuclear operation began. And just to point out that we don't have any dose estimates for the 248 persons who were out of the area but it's presumed to be low.

They did not demonstrate a dose response effect. However, they do mention that for about 60 percent of the in-area residents, they could not classify them into either a high or low exposure category and so they mentioned that the results should be interpreted with caution.

And -- DR. TEMECK: I think that's fair.

Just making some observations on Chernobyl versus Hanford, in general, and I made this point earlier today, thyroid cancer has a

low background rate of occurrence and when you're making a risk estimate
for a disease with a low background rate of occurrence, the greater the
sample size, in general, the greater is your statistical power to
demonstrate a difference if one is present.

I wanted to make the point that with Chernobyl we have
several million children who were exposed. In Hanford, we have several
thousand who were exposed. DR. TEMECK: Right. Of course, there are other differences
and I was going to go into some of those additional differences and
clearly there was a difference in the duration of exposure between
Hanford and Chernobyl and there is -- has been reported -- at least this
based on very limited data that possibly your risk decreases if you
spread the exposure over time, which might have been, because you then
allow cellular repair mechanisms to come into play. I don't if maybe
that was a factor that was involved. This is conjecture but certainly
that was another difference.

You mentioned, Aby, certainly what was released was different in Hanford. It was an iodine 131. Where Chernobyl we again
go back to this issue that we were dealing with a combination of iodine
131, gamma radiation, the shorter lived isotopes of iodine and it's just
very difficult to try to precisely sort out exactly what contribution
each one of these factors made in the overall incidents that we saw with
thyroid cancer.

MOkay, we do feel that based on the Chernobyl data that it is
prudent to KI prophylax and to regard it as an adjunct to other

counter-measures, evacuation, sheltering, agricultural and food control,
all of which are aimed, obviously, at reducing radiation exposure to the
population.
We will be revising, as I mentioned, our '82 Federal
Register Notice and we're going to make it very clear in the Federal
Register Notice that this is solely a guidance to the states regarding
the safe and effective use of KI for thyroid blocking and that it is the
responsibilities of the states and the local health authorities to
formulate emergency response plans.
Again, we'll make it very clear that this is an adjunct. It's not to replace the primary mode of dealing with these accidents
which, of course, as we know is evacuation. You have to initiate
agricultural and food control measures. This is just an adjunct to
these. We will also make it clear, as we've stated earlier in this
conference, that the KI protects only the thyroid gland and clearly only
from inhaled or ingested radioiodine. we do know at least from
Chernobyl that it's this group, the fetuses, newborns, infants and
children and particularly in the age range of up to four years of age
that are really the most vulnerable age group to radiation induced
thyroid cancer. Again, we do have uncertainties as does everybody else
and what the really precise role was of iodine 131 which was released at
the time of this accident.
However, we do know that you have to prophylax with KI
before exposure has occurred in order to maximize thyroid blocking. You

certainly are going to have still a substantial blocking effect if you
administer KI three to four hours, up to six hours post-exposure but to
really get the maximum thyroid blocking, you have to prophylax before
exposure occurs. And we understand that at the time the accident is
occurring, that it's very difficult really to predict precisely how much
radioiodine is going to be released, so you may predict for example,
that -- you know, that there is a five rem release and the five rem, it
could be actually more than that.

So there's a lot of uncertainty from the perspective of
trying to project how much is being released at the time the accident
has occurred. we're left with a number of unanswered
questions and what is the best judgment that we can provide based on the
available data that we have is that we feel that KI should be used as a
prophylactic adjunct to other measures for this particular age group
when they are likely to be exposed to radioiodine.

CHAIRMAN MOHSENI: Do you have a threshold level or just yea or nay on the bottom? Exposure of what level, is there a --

DR. TEMECK: Based on the dose response relationship that we
have seen in the Nature paper which was reported in 1998, that an
increased incidents was reported. Again, this is reported as mean
iodine 131 dose to the thyroid. That at a mean dose of five rem -- and
we don't have the ranges on that, that we did definitely see an
increased risk at five rem and five rem was actually intervention level
that Poland used in their prophylactic regiment.

However, it's -- at least from the best available

reconstruction of the data that we do have at present, it appears as if
it is a linear dose response relationship. So even if you extrapolate
down to one rem, you're not coming down to zero risk. Still the risk is
increased even down to one rem and given -- I'm going to go further into
what is the safety profile of KI and we do feel that when you give KI
either as a single dose or one or two doses, it's very safe. And that
weighed against the fact that we do have -- and again this is, you know,
an extrapolation, that there will be in this very sensitive age group a
-- that they are very sensitive to radiation induced thyroid cancer,
that we do feel at this point in time, and this is a draft, nothing is
finalized, that we would recommend even at one rem projected exposure,
that KI prophylaxis be used in this age group.

MR. McNUTT: That age group is four and under?

DR. TEMECK: I'm sorry, Bill.

MR. McNUTT: Is that four and under the age group?

DR. TEMECK: No, where we say fetuses, newborns, infants and
children, we're referring to those who would be up to either age 18 --
probably age 18.

MR. McNUTT: So in the one place you used 15 or was that the
other study, here you're using 18.

********** MR. WILDS: You know, you talked about the logistics of KI
in schools.

DR. TEMECK: Yeah.

MR. WILDS: And, you know, we're looking at logistics from a
broader standpoint.

DR. TEMECK: Yeah, I understand. DR. TEMECK: Our thoughts right now are either single dose,
two dose or three dose. That's what we have under discussion right now.

//

MR. McNUTT: At what level, 130 milligrams or --

DR. TEMECK: Again, we're looking more into the safety issue with the neonates on the transient biochemical hypo-thyroid that's occurring. We have to get the data from Warsaw. I mean, that's going to factor into also what dose we're going to recommend by age groups.

So that's not decided at this point.

MR DR. TEMECK: Yeah, but you see also logistically though, I mean, if you're going to let's say recommend that you have a stockpile of KI in high schools, and at the time an accident is occurring it would be best just to prophylax all those through high school to cover any possibility that they would be at an increased risk.

**contraindications:**

Temeck: 12 newborns out of over 3,000 who received KI on the second day of life that developed this biochemical hypo-thyroidism. It was a transient phenomenon. Two weeks later all of them had normal thyroid function.

So in terms of incidents, it's very low. We'll look specifically at the thyroid function data in those 12 newborns, but let's say that if it does happen, that group though is at greatest risk though for radiation induced thyroid cancer, so you want to protect them as best as you can.

So that would not obviate the need to prophylax because of the fact that you saw a 0.4 percent incidents of transient biochemical hypo-thyroidism. What it could factor into is into the dose that we might recommend but in those newborns we might recommend that if a

newborn receives KI that they then be monitored let's say with a serum
TSH level which can be readily done and it can be readily treated. And
actually it's a transient phenomenon so you probably wouldn't even need
to treat it.

DR. TEMECK: Certainly, I mean, because you're not just looking at thyroid cancer. You're also going to have to be concerned about radiation induced hypo-thyroidism and nodules, all of which have been reported to have an increased incidents. So there the concerns are somewhat differently so you want to prevent the deterministic effects of the hypo-thyroidism, the nodules in emergency workers. They would not be susceptible, per se, to thyroid cancer, so it's a different objective for giving the KI to emergency workers.

MR. SIMPSON: So you anticipate there would be some recommendations for older people.

DR. TEMECK: Yes.

*****CHAIRMAN MOHSENI: Okay, let me ask you this; the iodine 131 has been pretty much visible in your slides and the discussions. Did the Hanford study effect your outcome at all or was that just -- didn't rise to the level?

DR. TEMECK: For that particular set of circumstances, and I mean that these are very unique situations what happened at Hanford.

CHAIRMAN MOHSENI: Simplified, you've got the only scenario pushing Hanford we've ever had where you have iodine 131, range, given range, powerful clinical studies of the individuals exposed, no correlation with thyroid disease, no impact in your assessment whatsoever?

DR. TEMECK: We did look at that and again we're going back

to one thing is 1) sample size which I did discuss. We have several
million children who were exposed with the Chernobyl accident versus
several thousand who were exposed at Hanford. That certainly played
into -- that was a factor for us.
Secondly, and I know Doctor Hamilton talked about the
2) uncertainties in the dose estimates. Whenever you're going back to try
to reconstruct exactly what were the iodine 131 doses to the thyroid as
opposed to directly measure them at the time when the accident is
occurring, you're always going to have uncertainties built in as to what
exactly the participants did receive.
R. McNUTT: Well, Doctor Hamilton, he said himself, you know, given the unique situation for the study around Hanford, dose
reconstruction and the time that the dose was accrued, given all that no
evidence of thyroid disorders or cancer. He then stated that there was
no question in his mind that radioiodine 131 causes thyroid cancer. So
he was -

**MR. WILDS: But, yeah, that's where we're getting in, what's
the risk versus the benefit and when we look at the risk, we're looking
-- we have to consider the risk of increasing the doses from other
components.
(give to CONN) DR. TEMECK: I'm talking about our clinical, medical risk.
The medical risk from short force of KI administration for thyroid
blocking is minimal.
MR. WILDS: Right, I know you talk about -- but I mean, from
my standpoint, we --

DR. TEMECK: Of course from your standpoint, of course.

MR. WILDS: -- have a totally different perspective.

DR. TEMECK: I understand.

DR. TEMECK: But, Aby, to answer your question, yes, we did -- we are looking very in-depth at Hanford.

CHAIRMAN MOHSENI: Good.

DR. TEMECK: But, you know, again, it's like trying to compare apples and oranges, you know.

CHAIRMAN MOHSENI: I'm not asking you to compare.

DR. TEMECK: Right.

DR. TEMECK: The reason that we find it very difficult to recommend a perimeter is because at the time that the accident is occurring, there are uncertainties in the severity of the accident, the isotope composition, the length and dispersion of the release when the accident is occurring. So it will have to be determined at the local level as to what distance from the site based on all of these characteristics of the particular release at which KI prophylaxis should be implemented

MR. NAWOJ: So these aren't projected doses we're dealing with.

DR. TEMECK: Right. That is correct.

CHAIRMAN MOHSENI: These are realized doses --

DR. TEMECK: Yes.

CHAIRMAN MOHSENI: -- not projected.

DR. TEMECK: Well, what we're saying is because uncertainty in projection, you might say that, you know, well, there is only -- let's say if we did a 5 rem intervention level for the vulnerable age group and -- but the 5 rem that was projected could be actually 10 rem in practice. That's the concern -- and you have to balance that against

the fact that you have to give the KI before the exposure actually occurs.

So that's why it makes it very difficult when you have such a vulnerable population and I don't know, you know, how much can I precisely say is due to iodine 131 or to gamma or to the short-lived isotopes. When you balance that medically against the fact that it's a very safe drug when given short-term, this is why we're saying that if there is -- it's projected that they are likely to receive radioiodine on the best estimate that's made at the time of the accident, that this vulnerable age group should receive KI prophylaxis.

CHAIRMAN MOHSENI: At what dose level again? Was it five or was it --

DR. TEMECK: We were using a one rem, extrapolating back the linear dose response relationship that we do have.

**********CHAIRMAN MOHSENI: For now, it's all draft, of course, that's what you're thinking of. Okay, one rem projected dose the vulnerable age group.

DR. TEMECK: The vulnerable age group we're defining as up to 18.

*******MR. McNUTT: Jean, let me get this clear.

DR. TEMECK: Yes.

MR. McNUTT: You are now saying that it would be recommended at those protections and not environmental measurements?

DR. TEMECK: It would be both, obviously, because you take environmental considerations into play in terms of deciding how far out you have to go. You know, is there a strong prevailing wind or is there

not. So that will play into how far you have to prophylax.

MR. McNUTT: I mean, by the time you do field measurements, it's too late in many cases.

MR. SIMPSON: I think Jean's only point in environmental was the wind --

DR. TEMECK: The wind, the prevailing wind.

MR. SIMPSON: -- not actual measurements. It's too late for that.

DR. TEMECK: That's right.

MR. SIMPSON: So the wind is the only aspect you were speaking to.

DR. TEMECK: Right.

MR. SIMPSON: The problem on the other side of that is we can't wait for the wind, as planners, to decide how far out we're going to go.

DR. TEMECK: Yeah, I know. I mean, there are problems. You're absolutely right.

MR. SIMPSON: Of course, the further out, the more time you have.

DR. TEMECK: The more time you have the farther out, yes, you are.

***DR. TEMECK: One of the things where we talk about, you know, we're saying that the states might consider pre-distribution and in that pre -- if they do decide on a pre-distribution program, they might consider giving KI, let's say in prenatal clinics or in hospital maternity wards so that it would be available at home. If a state of emergency is declared, then it wouldn't matter where the newborn is, if they're in home or in hospital. I mean, they should be given then the

Plan idea
Hospital distribution for newborn

KI at the time if that's the decision that is made on the local level.

MS. KEY: So are you saying that in an area -- I'm wondering if you're suggesting is that every child in a hospital near a power plant should be sent home with a dose of KI.

DR. TEMECK: I think it should be taken under consideration.

MR. WILDS: What about just children in general? A. VOICE: You have it at home and in the school and in the hospitals.

DR. TEMECK: Well, the states will work out as to where they want to have the material stockpiled if they decide on a pre-distribution program and who should get it. I mean, those are decisions we feel should be left up to the states and the local public health authorities. We're just suggesting those as possible scenarios for considerhese things. So somebody at a reception center has less chance of being before and if it's in their home and you somehow notify them at that point.

DR. TEMECK: That's preferable, yes.

MR. NAWOJ: Would it be useful to make KI available in the appropriate dosages over the counter to the general public?

DR. TEMECK: Yes.

MR. NAWOJ: How would we go about doing that?

DR. TEMECK: There is voluntary purchase that's available.

MR. NAWOJ: There's what?

MR. SIMPSON: We were talking about it before. The liquid form is available. No one in this group or any of our research or our medical people in Pennsylvania have yet been able to find a pill form -- and obviously we'll talk later about what needs to happen to pills, it

does not appear to be available except in liquid form at this point.

DR. TEMECK: For the public.

MR. SIMPSON: For the public, yes. The governmental agencies, the power plants, they seem to be able to buy it and I'm assuming there's a quantity thing, you buy it by cases --

DR. TEMECK: Oh, I see, you're saying --

MS. SIMPSON: -- but talking to the pharmacies it is not --

DR. TEMECK: -- for individuals.

MR. SIMPSON: -- not available, does not appear to be available

*****MR. LANTZ: So would FDA say that KI is a safe and effective drug given to ~~neonates at home?~~

DR. TEMECK: Yes, in the state of an emergency situation absolutely.

MR. WILDS: This is sort of a non-medical question but you may be the best person to answer it. How many -- what percentage of people that take KI that really don't have a clinical reaction? How many could I expect that think they have a clinical reaction and that are going to flood my hospitals?

DR. TEMECK: Oh, from the Poland experience, I mean, you're there 90 whatever percent it was, I mean there were no problems whatsoever. DR. TEMECK: Actually, we've gone through this fairly much.

The number of doses, as I said, were deciding on at this point in time we're wrestling with single dose versus two dose or three dose, just to let you know where we're standing on that issue right now. Okay.

Obviously, you know, you don't want to delay evacuation by distributing

KI. We're also going to include that in the Federal Register and all this.

If you can avoid -- you know, if you can get out of the area, certainly that is preferable than to taking KI, but, again, you know, can you be certain that you haven't been exposed to the radioactive plume. I mean, that's always the other side of the coin.

Okay, but this is pretty standard stuff that I have here on this slide.

Okay

DR. TEMECK: We'll be calling Ambex and Carter Wallace is speaking with them about getting the tablets available for individual voluntary purchase. DR. TEMECK: Oh, I think that clearly that we will do everything that we can to put pressure on them to get it available for individual voluntary purchase. DR. TEMECK: Yes. Okay, let me just -- dosage by age group,

Get voluntary drug store supply

like I said it's not yet been determined. We understand the logistics of dividing doses into four different categories by age group. Again,

I'm going to be speaking with Doctor Mooreman (ph) in Warsaw about the neonatal hypo-thyroidism that he reported in his paper and so we need to get a little bit more information on that issue and then we will be wrestling again with dosing by age groups.

I make a general statement here but I can expand as much as you want but it's in our very in-depth assessment that a short force of KI, what I mean by that, single, two dose, three dose for acute thyroid blocking poses minimal risk. And when I say here that maybe there may be certain special circumstances where this may be -- potentially cause

a problem, I'm referring to the Poland study and we're going to look into that further.

Contra-indications you've heard from Aubrey this morning so I won't go into that but we'll address that very clearly in detail in our document. It is very -- there's not many contra-indications. This is what I'm saying here is about, you know, with a very low intervention level for newborns, infants, children that the states might consider free distribution and especially targeting the vulnerable age groups.

And some of the issues for public education that the states might consider again, is instructing the public on where they can get it, the number of doses they should take, what exactly the dose is, what are the side effects, who shouldn't take the KI, general issues of that nature.

This is just, you know, a standard precaution about KI, that you should protect it from air, light, moisture and heat. It has a shelf life of five years. I did verify that with Carter Wallace because I think the issue was raised at our last meeting that it might have a shelf life of three years and that Carter Wallace did tell me it's five years. I'm sorry?

DR. TEMECK: I don't know about the coating. I can say if you keep it protected from air, light, heat and moisture, you keep it wrapped in foil, I don't know about indefinite but certainly probably a lot longer than five years, but we don't have data on that.

DR. TEMECK: So you know, this is just from my knowledge.

The last point is alternative forms. I mean, clearly KI was

chosen because of the fact that it has a very rapid onset of action. It
gives almost thyroid blocking if you take it just prior to exposure. It
lasts 24 hours. It is a very safe product to use, which is why KI was
chosen as the model so to speak to use. But yeah, there are other forms
of stabilize iodine and we'll discuss those in the document.
-will FDA have a position by September as you --
DR. TEMECK: We hope to, Aby. It's been voluminous the
amount of data we've been going through and we're trying to do
everything as best as we possibly can. I can assure you of that. It's
a huge task and you appreciate all of the complexities associated.
We'll do everything we can to meet that September deadline. CHAIRMAN MOHSENI: Remember all these things are going to
come together by the end of the year; the rule-making, the guidance
document, the FRPCC position, which were all dependent, to a great extent
on how FDA would change its current 1982 current position.
MR. McNUTT: Well, I can assure you that the FRPCC guidance will not be guidance until the final FDA guidance is published.

FEP stages KI — players
1. NRC rule
2. NRC guide
3. FRPCC
4. FDA

******** [redacted] decision. That's the bottom line. We tell them the best information out
there and put the necessary caveats so that they understand the lack of
enough information in Chernobyl that connects it directly to what -- but
given the fact that FDA looked at what's available out there, not what's
enough, they could always use more information, but today what they saw
then FDA says, "This is the conclusions we drew in spite of the fact of

that lack of certain desired parameters that we couldn't find to corroborate to the point where you have 95 percent", whatever confidence level you want.

But what we want to offer ultimately is so that the states have the benefit of all the pros and cons of what are they actually not getting if they don't go with KI and you know, are getting with KI and the pros and cons of distribution. So we do have to characterize the risk as you understand it best from Chernobyl and the history of all the studies done that shed more light. This is not an easy task because we want to avoid encouraging or discouraging in this document the FDA position has inherent in it the best public health position that FDA can come up with. So that speaks for itself but the document is not one that either discourages the states or local governments or the tribes or encourages them one way or the other.

They have to look at their situation, the states and locals, and decide for themselves if this is how -- what they want to add as an adjunct or a supplement protective action and we have our statements up front, it's not something for ingestion pathway; it's not -- it does not substitute or replace evacuation, it is -- you know, all the caveats that we have over the years collected in the back of our minds will all appear up front.

And then FDA's position is a federal position that has its inherent encouragements for public health but it's not the one that -- you know, that doesn't mean the document has to take side either way.

And that's the difficulty and the challenged we're faced with because it
has to be a document that has the entire set of parameters that a
decision maker has to look at and our best pros and cons that we can
offer for them to make that informed decision.
Our target remains -- our schedule remains unchanged as I
understand it, Jean, tell me if it's otherwise, that by the end of this
year we're still targeting that we will have all these things come
together. That the FDA will somehow have received some comments back
from the public.
She has his number!)DR. TEMECK: Okay, Aby, just from listening now to what you
just said, you also want us to review and critique all the other nuclear
accidents as well?
CHAIRMAN MOHSENI: Nuclear accidents, you mean --
DR. TEMECK: The Marshall Islands, Nevada, et cetera?
DR. TEMECK: No, we're not ready to put out a position, Aby.
You know, again it goes back will our Federal Register notice be out for
public comment in the fall is what you're asking. I can't promise that.
I mean, we're moving as fast as we can without compromising quality of
what we're doing. And we're making every effort to move as rapidly as
we can. I just cannot promise that we're going to have that out for
public comment in September.
ABY SCAM IN BREW)
MR. SIMPSON: Two comments, let me do the second one first.
As I indicated earlier, I think that perhaps there is a middle position
there as well, that we go through and we put the draft together with or
without Jean's comments. Clearly, if Jean does not have it, I think

that kind of ends any possibility of it going out for public comment.

But with or without Jean's comments, we might recommend to the Commission that here is a draft for their review but we do not believe it is ready yet to go out. So that's another possibility.

CHAIRMAN MOHSENI: Very good, I like it. (scam called)

MR. SIMPSON: Switching to another point back to FDA and what they're looking at clearly, as Aubrey or whoever said, we not in any position nor should we be to tell FDA what they need to look at.

However, when you go out for Federal Register notice, almost assuredly only of the things you're going to get if you haven't mentioned, you know, the other studies in there somebody is going to say, "Why haven't you mentioned them"?

DR. TEMECK: You are absolutely right.

MR. SIMPSON: So let me just throw that in the box to think about.

DR. TEMECK: I think that, yeah, I 100 percent agree. It's certainly true.

MR. SHERIDAN: The agency seems pretty clear on requiring KI for the 18 and under group.

DR. TEMECK: Uh-huh.

DR. TEMECK: Clearly, you know, what we're -- if there's voluntary purchase available, which I understand there's not right now, but if there is, I mean, that's going to simplify matters dramatically, clearly. My personal position on -- because now it's just a personal position, on recommending KI for older age groups, certainly in those who are less than 40 you have nothing to lose by taking it. There is a small risk there. I mean, it's very small but it is there. The risk of

KI administration is practically, is very, very tiny. So it probably
would be beneficial to have it available in that age group.
Over 40, again, you know, based on what we've seen Chernobyl
and also Hiroshima and Nagasaki, I mean, you're virtually -- you're at
no increase risk of getting thyroid cancer secondary to a radiation
exposure if you're over 40 based on that data. And yet, the side
effects from KI administration certainly start to go up. So unless, you
know, you have a very high exposure, I think that it may well be that
there would be no need to take KI in the older group but that's a
personal position.
CHAIRMAN MOHSENI: Usually and so those are some of the new
things that are coming out. And emergency workers, that's another
interesting item for you to consider. Those are individuals who
actually are going to go in a known contaminated area, potentially
contaminated area to help with the public. Right now, as you know, the
federal policy is to give KI to them at 25 rem projected thyroid dose.
You may be changing both the strength and who knows, the dose level. So
all those things are repercussions. Yes.
CHAIRMAN MOHSENI: Okay, what about another issue that came
up, Jean, was whether or not you needed medically trained individuals to
give out potassium iodide. Is that something that FDA can clarify? Is
that a requirement?
DR. TEMECK: Certainly. You mean in the case of an emergency?
CHAIRMAN MOHSENI: Yes.
DR. TEMECK: Oh, certainly not. I mean, that's just going

to complicate them more. R. SHERIDAN: And, you know, I think addressing it by
requiring the teachers to dispense it only in emergencies would be
appropriate.

Schools

DR. TEMECK: Oh, of course, absolutely, only in emergency,
you know, because you want to get it to the children as quickly as
possible and the teacher is right there on the spot. She just would
hand one out to each child in the classroom. DR. TEMECK: Right, I mean, severe ones, I really -- I mean,
if you develop an allergic reaction, maybe you could, you know, get a
skin rash or you might get some swelling. I don't really see that as --
maybe in a very small percentage, I mean, .5 percent of individuals
there may potentially be a problem.

MS. PEPPER: But time frame, does it happen right away?

DR. TEMECK: No, not immediately. We're talking about, you
know, within a few minutes or hours, generally not, no, it doesn't.
CHAIRMAN MOHSENI: The bet was whether or not FDA would
elect the threshold to be 5 rem --

**** DR. TEMECK: Or 1 rem.

CHAIRMAN MOHSENI: -- or 1.

DR. TEMECK: And you said 5 rem.

CHAIRMAN MOHSENI: And I said 5 and I said, Jean's body
language tells me 5. I lost.

DR. TEMECK: Oh, no, I'm sorry Aby.
MR. GODWIN: But it's not out yet either.

DR. TEMECK: That's right, there's hope yet.

MR. GODWIN: Don't pay till it gets in print.

DR. TEMECK: That's true. Very good, absolutely.

CHAIRMAN MOHSENI: Well, that's a new bet. I lost this one
already. This is a new one. I'll bet on it the next time. CHAIRMAN MOHSENI: On the record. There were some
interesting information that we heard today. It appears that changes of

some significance may occur in the FDA position and as you noticed,
those changes are yet to be assessed in terms of impact on overall
existing planning around plants. The question was raised in the break
we had as to whether or not whatever FDA comes up with, is that going to
be put in a context by FEMA, NRC, probably FRPCC, in terms of the
impacts in may have on the FEMA positions on changing requirements, if
you will, or not requirements but guidance.

And of course Bill McNutt is here and he witnessed
first-hand those changes, how those changes might effect emergency
planning if they materialize with a big if. You know obviously, that's
a big if. Bill, do you want to make any comments as to would you
anticipate that FRPCC would probably have to do further work after FDA
position becomes clear to us as to what it is to assess its impact and
so forth?

MR. McNUTT: I don't think there would be more guidance.
There might be changes.

CHAIRMAN MOHSENI: Okay.

MR. McNUTT: You know, FDA, they've had their guidance
issued for 16 years, 17 years, I guess and, you know, we just allude to
it. We don't mention it. We just say, "That's the guidance, the
cognizant federal guidance on the use of KI".

CHAIRMAN MOHSENI: Yes, pre-distribution, yes, correct.

MR. GODWIN: She talked about pre-distribution and we should
note it in the record that really she was talking about distribution in
advance of the accident

MR. GODWIN: Because that's a very important point for the
persons how read it later. So, you know, don't think that just because

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it's come out the first time in the Federal Register or even what she said today is necessarily going to be what comes in the first notice. There's still awhile for changes. (THEY ARE ALL SQUIRMING) CHAIRMAN MOHSENI: No, no, I understand that but remember this document is not the policy document. This document is the pros and cons -- regardless of who pays, pros and cons of having KI or not having KI, pros and cons of various distribution mechanisms and the best assessment we could do in terms of reflecting the three states' experiences, if you will, and the program costs, calculated, estimated by whatever means we have here. MR. SIMPSON: I understand, but I think there is a difference clearly when we talk about the value and cost benefit as to who is paying for that. If the state is not paying for some portion or all, that is a different negative or lesser negative than if the state is paying for all costs including purchase. I think definitely in terms of pros and cons it's a big change in what is pro or what is con or to the degree of what is pro and con.

(ASSESS UTILITY ANYWAY WHO CARES NRC OR STATE?)

******CHAIRMAN MOHSENI: Especially when the doctors, both of them said that I would take it under/over 18 and they're not even entering into a radiation area.

MR. SIMPSON: But emergency workers now at 25 rem that's when they're told to take it. MR. SIMPSON: Now, the scenery has shifted. We're dealing now with this disparity between the general public who are taking it at one rem or RAD and emergency workers who are still tied to 25.

MR. GODWIN: Or zero, they may not even take it.

****stategy
MR. SIMPSON: -- I think my suggestion earlier still applies, that we go ahead and we draft the document, hopefully with input from Jean that is able to be used, even if it's not totally definitive and at that point we look at that draft document and we, as a committee, recommend to the Commission that they put it out for comment or that it is there for their use but not ready to go out for comment.

CHAIRMAN MOHSENI: Absolutely.

********ABY
CHAIRMAN MOHSENI: We hear you. I think we did raise good questions for Aubrey to take to WHO. We don't know where WHO will go with those comments. We do have concern about the basis for their conclusions that they draw, no question about it. We went and we were lucky, I think. I personally think we were very lucky that the Hanford Thyroid Disease study came to fruition when it did. We put it on the table. It's there on the table. Does it impact the linear non-threshold relationship, dose relationship?

I think it -- personally, I think it does. FDA has to be convinced of that. Windscale is another event that had the iodine concentrations in the environment. We are going to reference that study. FDA has to take a position that jives with realities and I don't know if they can be that selective in terms of just picking and choosing the data that supports a certain position.

Whatever position they come up with has to be supported scientifically with all the historical data we have. And those are some

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of the comments we will provide at the right time to FDA even though we could definitely spend more time arguing and debating the issues in a scientific forum with scientists on this issue. But we have a schedule and we are going to -- I think to some extent the fact that this document will have to be published will force FDA to move along faster than just taking its time to evaluate every historical event which I thought was done before, you know, before '82, but if need be they can go back and revisit those historical events further.

MR. McNUTT: Aby, I don't believe that the FDA has any pre-disposition in this matter. I think they're making an honest and genuine analysis.

CHAIRMAN MOHSENI: Absolutely, nobody claims the opposite. I think they're going at a great pace. That's wonderful, as I said.

What we saw today was much better than what I thought. All we're doing is making sure the data used is consistent with the data we've seen to make sure we understand how the conclusions are drawn. That's all and, you know, that Hanford health effects, the Windscale event, Marshall Islands, whatever data there is, historic data, has to be used properly to make the best conclusion possible, no question about it.

I never claimed anything else, Mr. McNutt, did I?

MR. McNUTT: I guess I must have misunderstood you.

NO, you didn't MR McNutt!